**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Confidential Draft No. 3 submitted to the Securities and Exchange Commission on November 12, 2019. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

**REGISTRATION STATEMENT
Under
The Securities Act of 1933**

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	81-2974255
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

**2945 Townsgate Road, Suite 110
Westlake Village, California 91361
(805) 418-5006
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

**Todd Franklin Watanabe
Chief Executive Officer
Arcutis Biotherapeutics, Inc.
2945 Townsgate Road, Suite 110
Westlake Village, California 91361
(805) 418-5006
(Name, address, including zip code, and telephone number, including area code, of agent for service)**

Copies to:

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**Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.**

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or and "emerging growth company". See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common Stock, par value $0.0001 per share	$	$

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) The proposed maximum aggregate offering price includes the offering price of additional shares that the underwriters have the option to purchase.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 12, 2019

PRELIMINARY PROSPECTUS

Shares

Common Stock

This is an initial public offering of shares of common stock of Arcutis Biotherapeutics, Inc. All shares of common stock are being sold by the company.

Prior to this offering, there has been no public market for the common stock. The initial public offering price is expected to be between $ and $ per share. We intend to apply to list our common stock on the Nasdaq Global Select Market under the symbol "ARQT".

We are an "emerging growth company" as defined under the federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our common stock involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 15 to read about factors you should consider before buying shares of the common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See "Underwriting" for additional information regarding compensation payable to the underwriters.

We have granted the underwriters a 30-day option to purchase up to additional shares of common stock from us at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on , .

Goldman Sachs & Co. LLC **Cowen** **Guggenheim Securities**

Cantor

Prospectus dated , .

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

TABLE OF CONTENTS

We and the underwriters have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is current only as of its date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

TRADEMARKS

The mark “Arcutis” and the Arcutis logo are our registered trademarks, and all product names are our common law trademarks. All other service marks, trademarks and trade names appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

MARKET AND INDUSTRY DATA

This prospectus contains estimates, projections and other statistical data and information concerning our industry, our business and the markets for our product candidates. Some data and statistical information contained in this prospectus, including market size and opportunity figures for our product candidates, are based on management’s estimates and calculations, which are derived from our review and interpretation of the independent sources, our internal research and knowledge of the industry and market in which we operate. Some data and statistical information are based on independent reports from third parties, including DR/Decision Resources, LLC, or Decision Resources Group, and Adelphi Group Limited, or Adelphi Group, as well as reports that we commissioned from third parties. Decision Resources Group makes no representation or warranty as to the accuracy or completeness of the data, or DR Materials, set forth herein and shall have, and accept, no liability of any kind, whether in contract, tort (including negligence) or otherwise, to any third party arising from or related to use of the DR Materials by us. Any use which we or a third party makes of the DR Materials, or any reliance on it, or decisions to be made based on it, are the sole responsibilities of us and such third party. In no way shall any data appearing in the DR Materials amount to any form of prediction of future events or circumstances and no such reliance may be inferred or implied.

This information, to the extent it contains estimates or projections, involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. The industry in which we operate is subject to risks and uncertainties due to a variety of factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the sections entitled "Risk Factors," "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See the section entitled "Special Note Regarding Forward-Looking Statements." Unless the context otherwise requires, we use the terms "Arcutis Biotherapeutics," "company," "we," "us" and "our" in this prospectus to refer to Arcutis Biotherapeutics, Inc.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. Our current portfolio is comprised of topical treatments with significant potential to address immune-mediated dermatological diseases and conditions, or immuno-dermatology. Our strategy is to identify and develop treatments against validated biological targets in dermatology that deliver a differentiated clinical profile that addresses major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product candidate, ARQ-151, is a topical cream formulation of roflumilast, a highly potent and selective phosphodiesterase type 4, or PDE4, inhibitor, which we are developing for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae and inframammary areas, as well as atopic dermatitis. PDE4 is an established biological target in dermatology with multiple PDE4 inhibitors approved by the U.S. Food and Drug Administration, or FDA. We have successfully completed a Phase 2b study of ARQ-151 in plaque psoriasis, and have treated more than 425 plaque psoriasis patients, demonstrating potential symptomatic improvement and favorable tolerability of ARQ-151 in this population. We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, and expect to report topline data in the first half of 2021. After holding a positive End-of-Phase 2 Meeting with the FDA in October 2019, we will initiate Phase 3 studies in plaque psoriasis in the first half of 2020 and expect to report topline data in the first half of 2021. We also have completed enrollment of a Phase 2a study of ARQ-151 in atopic dermatitis, and expect to report topline results from this study by the end of 2019. If successful, we plan to initiate a Phase 2b study in atopic dermatitis in the second half of 2020 with topline results in the second half of 2021. In addition, we are developing ARQ-154, a topical foam formulation of ARQ-151, and will advance this product candidate into Phase 2b studies in both scalp psoriasis and seborrheic dermatitis in Q4 2019/Q1 2020, and expect to report topline data in Q4 2020/Q1 2021 with respect to scalp psoriasis and the second half of 2020 with respect to seborrheic dermatitis. Beyond this, in 2020 we also plan to initiate clinical studies of ARQ-252, a potent and highly selective topical janus kinase type 1, or JAK1, inhibitor for the treatment of hand eczema and vitiligo. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

The Major Unmet Need Across Our Initial Targeted Indications

Dermatological diseases such as psoriasis, atopic dermatitis, seborrheic dermatitis, hand eczema, alopecia areata, and vitiligo affect hundreds of millions of people worldwide each year, impacting their quality of life, and physical, functional and emotional well-being. There are many approved treatments for these conditions, but a large opportunity remains due to issues with existing treatments. Topical treatments are used for nearly all patients, but are limited by one or more of the following: modest response rates, side effects, patient adherence, application site restrictions, and limits on duration of therapy. Topical corticosteroids, or TCS, are commonly used as the first-line therapy for the treatment of inflammatory skin conditions such as psoriasis and atopic dermatitis. While many patients see improvements, long term TCS treatment carries the risk of a variety of significant side effects. As a result, TCS are typically used intermittently, which can lead to disease flares. In psoriasis, vitamin D analogues have demonstrated lower response rates than TCS and are frequently irritating. In atopic dermatitis, topical calcineurin inhibitors, or TCIs, and Eucrisa have lower response rates than TCS and are associated with application site burning. TCIs also have a boxed warning for cancer risk.

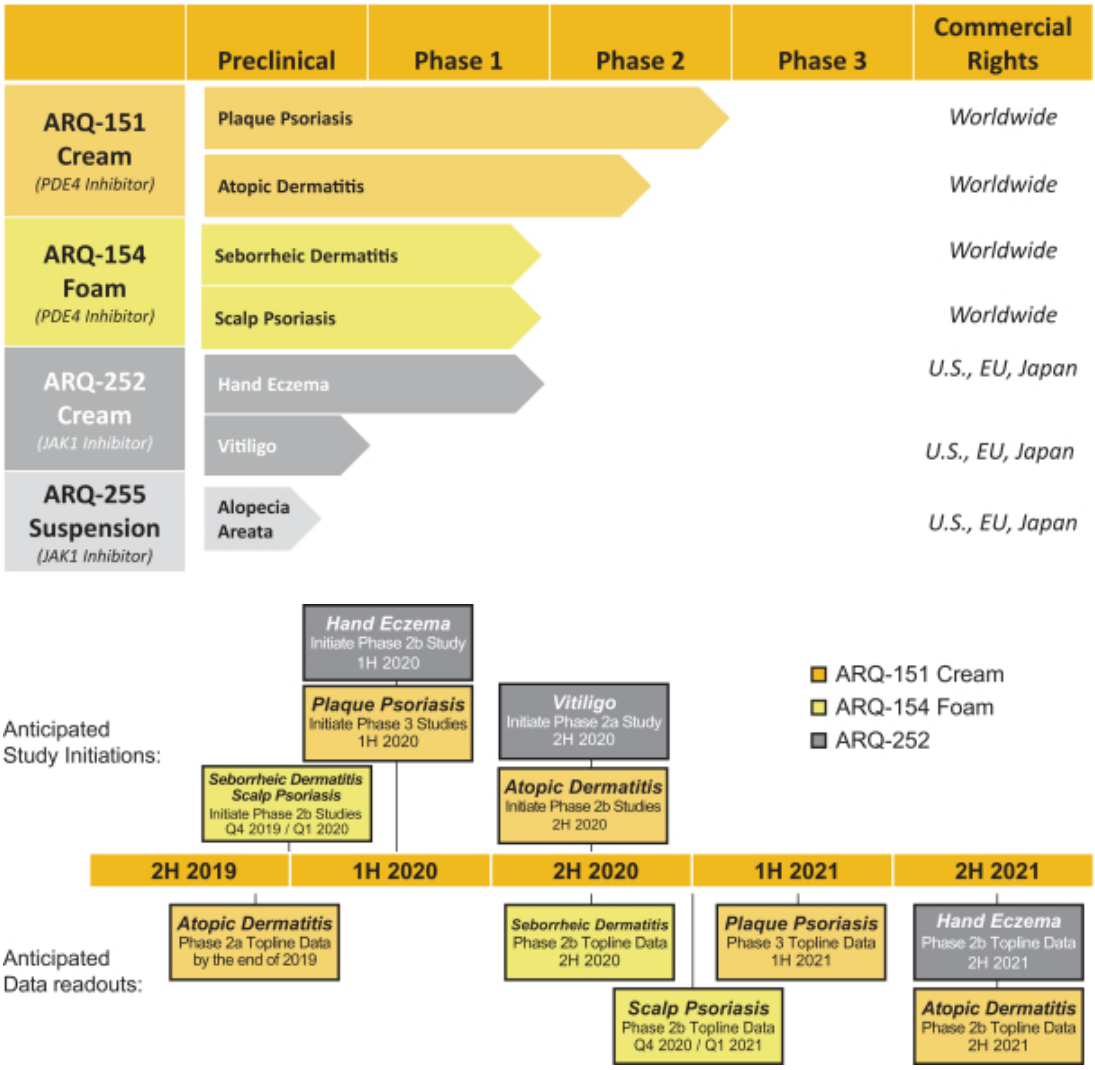
Biologic and systemic therapies are also available, but are indicated for a small percentage of the affected population. Biologics for psoriasis and atopic dermatitis have shown impressive response rates but are only indicated for patients with moderate-to-severe forms of disease, are expensive, and often face reimbursement and access restrictions. Use of oral systemic therapies such as methotrexate and Otezla are also limited to more severe psoriasis patients and have significant side effect risks. Additionally, many patients on biologic and systemic therapies still require adjunctive topical therapy.

Given the limitations associated with TCS, other topical therapies, biologics, and systemic therapies, we believe patients with inflammatory skin conditions are dissatisfied with their current treatment options. We believe that there is a significant opportunity to leverage developments in other fields of medicine, particularly inflammation and immunology, to address the significant need for effective chronic treatments in immuno-dermatology. Our initial focus is to address patients' significant need for innovative topical treatments that directly target molecular mediators of disease, have the potential to show significant symptomatic improvement, maintain a low risk of toxicity or side effects, and are suitable for chronic use on all areas of the body.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Our Pipeline

The following charts summarize our product pipeline, including our lead product candidate, ARQ-151, and our upcoming anticipated milestones.



ARQ-151

Our lead product candidate, ARQ-151, is a topical cream containing roflumilast, a PDE4 inhibitor, that we are developing to treat plaque psoriasis, including intertriginous psoriasis, and atopic dermatitis. PDE4 is an intracellular enzyme that regulates the production of pro-inflammatory and anti-inflammatory cytokines and cell proliferation. Roflumilast is a potent PDE4 inhibitor that was approved by the FDA for systemic treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease, or COPD, in 2011, and has shown greater potency based on IC50 values (the concentration

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PURSUANT TO 17 C.F.R. SECTION 200.83**

at which a biologic target's activity is inhibited by 50% and a non-clinical measure of a drug's potency) than other PDE4 inhibitors, including the active ingredients in Eucrisa and Otezla. Based on the clinical data we have generated to date, we believe ARQ-151 has the potential to offer symptomatic improvement similar to high-potency steroids, a favorable tolerability profile, the ability to treat chronically, and little to none of the application site skin reactions associated with many existing treatments.

In July 2018, we executed a licensing agreement with AstraZeneca AB, or the AstraZeneca License Agreement, for exclusive worldwide rights to roflumilast, the PDE4 inhibitor used as the active pharmaceutical ingredient in ARQ-151, as a topical product in humans solely for dermatological indications. We have built our own intellectual property portfolio around topical uses of roflumilast, with issued and pending formulation and pharmacokinetic patents/applications in the United States and other jurisdictions from four distinct patent families, which should provide us with exclusivity at least through 2037 for the formulation that is intended to be marketed.

We have completed two randomized, double-blind, vehicle-controlled Phase 2 studies in plaque psoriasis with ARQ-151, including a 331 patient multinational, multi-center Phase 2b study and an 89 patient multinational, multi-center Phase 2a study. Both studies have demonstrated significant reductions in the signs of plaque psoriasis and ARQ-151 has been well-tolerated in this population. In our Phase 2b study, ARQ-151 also demonstrated significant reductions in the signs of psoriatic plaques in the intertriginous regions, as well as favorable tolerability in those areas. The table below summarizes results from the Phase 2b study.

		Phase 2b (ARQ-151-201)			
	% of Patients	0.3% Dose (n = 109)	0.15% Dose (n = 113)*(a)*	Vehicle (n = 109)*(b)*	*p-value (0.3% vs. vehicle)*
Week 6	**% IGA of Clear or Almost Clear**	28.0	22.8	8.3	<0.001
Week 8	**% IGA Success***(c)*	32.2	24.5	9.8	*<0.001*
	Mean % CFB in PASI	(53.7)	(53.5)	(18.8)	*<0.001*
	% PASI-75	31.3	23.0	13.2	*0.002*
	% PASI-90	16.9	7.4	6.0	*0.015*
	% Intertriginous IGA Success*(d)*	87.1	60.9	36.1	*0.007*
	% WI-NRS (4 pt Δ)*(e)*	64.6	58.2	42.3	*0.01*
TEAEs	**% TEAE**	38.5	27.3	29.9	—
	% Tx-Related TEAE	6.4	2.7	6.5	—
	% SAE	0.9	0.9	1.9	—
	% D/C due to TEAE	0.9	0.0	1.9	—

The abbreviations used in this table include the following: Change from baseline, or CFB; Investigator's Global Assessment, or IGA, a 5-point scale for evaluating plaque psoriasis severity; Psoriasis Area and Severity Index, or PASI; Treatment-Emergent Adverse Events, or TEAE; Serious Adverse Events, or SAE; discontinuation, or D/C.

(a) For safety analyses, n = 110.
(b) For safety analyses, n = 107.
(c) IGA Success was defined as IGA = 0 (clear) or 1 (almost clear) PLUS a 2 point change from baseline.
(d) Intertriginous IGA, or I-IGA, Success was defined as I-IGA = 0 (clear) or 1 (almost clear) PLUS a 2 point change from baseline. I-IGA Success analysis was performed in subjects with baseline I-IGA ³ 2.
(e) Represents % of patients with baseline Worst Itch-Numerical Rating Scale, or WI-NRS, ³ 6, who achieved at least a 4-point improvement on the WI-NRS.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

We have also completed one Phase 1 study of ARQ-151 in atopic dermatitis and are in the process of conducting a Phase 2a study. We have completed enrollment with 136 adolescents (ages 12 and above) and adults with atopic dermatitis. We expect to have topline results from this study by the end of 2019. If the topline results from Study ARQ-151-212 are positive, we plan to initiate a Phase 2b study in atopic dermatitis in the second half of 2020 with topline results in the second half of 2021.

ARQ-154

We are also developing ARQ-154, a foam formulation of ARQ-151, for treatment of seborrheic dermatitis and scalp psoriasis. We designed ARQ-154 as a topical foam version of ARQ-151 to overcome the challenges of delivering topical drugs in hair-bearing areas of the body. Based on the results of our Phase 2 studies with ARQ-151, we believe that ARQ-154 has the potential to be well-suited for treatment of scalp psoriasis and seborrheic dermatitis and will be similarly well-tolerated in these populations. We plan to initiate Phase 2b studies for ARQ-154 in seborrheic dermatitis and scalp psoriasis in Q4 2019/Q1 2020. We believe that ARQ-154 will offer physicians and patients a highly differentiated clinical profile that is ideally suited to address unmet needs in the topical treatment of scalp psoriasis and seborrheic dermatitis.

ARQ-252

ARQ-252 is a potent and highly selective topical small molecule inhibitor of JAK1 that we are developing for hand eczema and other inflammatory dermatoses. JAK1 is one of the janus family of non-receptor protein tyrosine kinases, or JAKs, including JAK1, janus kinase type 2, or JAK2, janus kinase type 3, or JAK3, and tyrosine kinase type 2, or Tyk2. Collectively, these kinases are involved in cell growth, survival, development, and differentiation of a variety of cells. We believe that due to its high selectivity for JAK1 over JAK2, ARQ-252 has the potential to treat inflammatory diseases without causing the hematopoietic adverse effects, such as anemia, thrombocytopenia, and neutropenia, associated with JAK2 inhibition.

In January 2018, we executed an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd. of China, or Hengrui, for the active pharmaceutical ingredient in ARQ-252 for all topical dermatological uses in the United States, Europe and Japan. The Hengrui License Agreement includes an option to license composition of matter patents in the United States, and these patents extend to 2034 for the bisulfate form of the active ingredient. We believe there is the potential to obtain additional protection for ARQ-252 through possible future formulation patents and other intellectual property.

We intend to initiate a Phase 2b study in adult patients with hand eczema in the first half of 2020, with topline data expected in the second half of 2021. We also plan to initiate a Phase 2a study in vitiligo in the second half of 2020.

ARQ-255

We believe that topical JAK inhibitor therapy for alopecia areata requires the drug to be delivered to the site of the inflammation, deep in the skin at the base (bulb) of the hair follicle. We have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin to the postulated site of inflammation in alopecia areata. If those formulation efforts are successful, we plan to enter the clinic with ARQ-255 as a potential treatment for alopecia areata.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Our Market Opportunity

We believe there are significant market opportunities to capture in each of our addressable markets.

Product Candidate	Mechanism of Action	Formulation	Indication	Primary U.S. Addressable Market Opportunity
ARQ-151	PDE4 Inhibitor	Topical Cream	Psoriasis	Approximately 2.0 million patients treated by dermatologists with topical therapies
			Atopic Dermatitis	Approximately 1.0 million patients treated by dermatologists with topical therapies
ARQ-154	PDE4 Inhibitor	Topical Foam	Seborrheic Dermatitis	Approximately 360,000 patients treated by dermatologists that have an inadequate response to first line treatments
			Scalp Psoriasis	Approximately 850,000 patients treated by dermatologists with topical prescription therapies
ARQ-252	JAK1 Inhibitor	Topical Cream	Hand Eczema	Approximately 7.0 million patients
			Vitiligo	Approximately 2.6 million patients
ARQ-255	JAK1 Inhibitor	Topical Suspension	Alopecia Areata	Approximately 6.2 million patients

Our Team

In order to capitalize on our opportunity, we have assembled a management team with deep development, formulation and commercialization expertise for dermatology products. Our management team has held key roles in numerous biotechnology and pharmaceutical companies with a dermatology focus, including Pfizer Inc., Amgen Inc., Gilead Sciences, Inc., Kythera Biopharmaceuticals, Inc., Verrica Pharmaceuticals Inc., and Fougera Pharmaceuticals Inc. Through these roles, our management team was integrally involved in the development, approval and/or commercialization of more than thirty FDA-approved products (including eighteen topical products) such as Enbrel, Jublia, CeraVe, Aczone and Xeljanz. This extensive experience provides us with unique insights and capabilities in dermatology drug development and commercialization.

Our Competitive Strengths

Our competitive strengths are key differentiating factors that form the foundation of our business strategy. We believe that leveraging these strengths will allow us to realize our vision of becoming a leading dermatology company. Our competitive strengths include:

- ***Harnessing the benefits of clinically validated targets in dermatology*.** We are focused on identifying, developing and commercializing best-in-class molecules against biological targets that have been clinically demonstrated to directly affect dermatological diseases. We believe this approach enables us to advance potentially transformative treatments over shorter development timelines, at lower cost, and in a manner that improves their probability of technical success.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

- ***Late-stage lead product candidate with a highly differentiated clinical profile.*** Our lead product candidate, ARQ-151, is a topical cream formulation of roflumilast, a highly potent and selective PDE4 inhibitor that was approved by the FDA for systemic treatment to reduce the risk of exacerbations of COPD in 2011. PDE4 inhibition is a well-established mechanism in dermatology, as supported by the PDE4 inhibitors approved by the FDA, including Eucrisa for the topical treatment of atopic dermatitis and Otezla for the systemic treatment of plaque psoriasis. ARQ-151 has generated what we believe is promising data in multiple clinical trials to date. We expect to initiate Phase 3 clinical trials with ARQ-151 in plaque psoriasis in the first half of 2020. We also have completed enrollment of a Phase 2a study of ARQ-151 in atopic dermatitis, and expect to report topline results from this study by the end of 2019. We believe that ARQ-151 will offer physicians and patients a highly differentiated clinical profile to address the significant unmet need in the treatment of plaque psoriasis and atopic dermatitis.
- ***Diversified, multi-asset pipeline addressing major shortcomings of existing dermatologic treatments.*** In addition to ARQ-151, we are advancing a portfolio of topically-administered product candidates addressing multiple immuno-dermatological indications with significant market opportunities, including seborrheic dermatitis, scalp psoriasis, hand eczema, vitiligo and alopecia areata. We plan to initiate Phase 2b trials by Q4 2019/Q1 2020 in seborrheic dermatitis and scalp psoriasis using ARQ-154, a foam formulation of ARQ-151, that is designed to overcome the challenges of delivering topical drugs in hair-bearing areas of the body. Additionally, with ARQ-252, a potent and highly selective topical JAK1 inhibitor, we plan to initiate a Phase 2b study in hand eczema in the first half of 2020 and a Phase 2a study in vitiligo in the second half of 2020. We also have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. We believe that due to their high selectivity for JAK1 over JAK2, ARQ-252 and ARQ-255 have the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition.
- ***Strong intellectual property.*** As of September 30, 2019, we own or have the option to exclusively license 15 issued or pending U.S. patents, 15 issued or pending foreign patents and three international applications filed under the Patent Cooperation Treaty, providing comprehensive protection for our product candidates. For ARQ-151 and ARQ-154, we have built our own intellectual property portfolio around topical uses of roflumilast, with issued and pending formulation and pharmacokinetic patents/applications in the United States and other jurisdictions from four distinct patent families, which begin to expire in 2037. Our patent protection includes an option to exclusively license four issued U.S. patents and four issued foreign patents providing protection for the active ingredient in ARQ-252 and ARQ-255, which begin to expire in 2033 with potential additional protection through possible future formulation patents and other intellectual property.
- ***Proven leadership team, with differentiated formulation expertise.*** Our management team has extensive expertise in the development and commercialization of dermatology products, having held key leadership roles at a number of leading dermatology companies and collectively, has successfully developed and/or commercialized more than thirty FDA-approved products. In addition, we have unique expertise with developing differentiated and proprietary topical formulations of compounds in order to optimize their performance in dermatology applications. We believe that the breadth of experience and successful track record of our management team, combined with our broad network of established relationships with leaders in the industry and medical community, uniquely positions us to build a leading, fully-integrated dermatology company.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Our Strategy

Our strategy is to leverage recent innovations in inflammation and immunology to identify molecules against validated biological targets in dermatology, and to develop and commercialize best-in-class products that address significant unmet needs in immuno-dermatology. Key elements of our strategy include:

- ***Rapidly develop and commercialize our lead product candidate ARQ-151 for the treatment of patients with plaque psoriasis and atopic dermatitis.*** We plan to initiate Phase 3 studies in plaque psoriasis in the first half of 2020 and expect to report Phase 2a topline data on the use of ARQ-151 in atopic dermatitis by the end of 2019.
- ***Expand our addressable market with ARQ-154.*** ARQ-154 allows us the treat patients with certain dermatological diseases in hair-bearing areas of the body like the scalp where a cream is not suitable. We believe ARQ-154 has the potential to offer patients symptomatic improvement similar to high-potency steroids in scalp psoriasis and may be superior to standard of care treatments for seborrheic dermatitis, while potentially maintaining a low risk of side effects and favorable tolerability.
- ***Continue to innovate and develop our product pipeline of therapeutics, which we believe has the potential to be best-in-class in immuno-dermatology.*** We plan to develop ARQ-252, a JAK1 inhibitor with a high relative selectivity to JAK1 over JAK2, giving it the potential to be best-in-class, for the treatment of hand eczema and vitiligo. We plan to initiate our Phase 2b study in hand eczema in the first half of 2020 and our Phase 2a study in vitiligo in the second half of 2020. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.
- ***Establish an integrated development and commercial organization.*** We believe the concentrated prescriber base of the U.S. dermatology segment provides us with the opportunity to build a fully integrated commercial organization and targeted sales force for the commercialization of our product candidates among dermatology specialists. To further enhance the value of our product candidates, we will selectively seek partners to commercialize our products outside of the dermatology specialist segment, and to develop and commercialize our products outside of the U.S. market.
- ***Evaluate strategic opportunities to in-license best-in-class dermatology assets consistent with our core strategy.*** We will continue to explore opportunities to in-license assets and develop them to address unmet medical needs in dermatology.

Risks Affecting Our Business

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects that you should consider before making a decision to invest in our common stock. These risks are discussed more fully in the section titled “Risk Factors” beginning on page 15 of this prospectus, and include the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and we have incurred significant losses since our inception. We anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

- Even if this offering is successful, we will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our future operating results to fall below expectations.
- Our business is dependent on the development, regulatory approval and commercialization of our current product candidates.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.
- Our estimated market opportunities for our product candidates are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited.
- We face significant competition from other biotechnology and pharmaceutical companies targeting medical dermatological indications, and our operating results will suffer if we fail to compete effectively.
- We currently rely on single source third-party suppliers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. The loss of these suppliers, or their failure to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- We may not be able to obtain, maintain or enforce patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.
- We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of ARQ-151, ARQ-154, ARQ-252, ARQ-255 or any future product candidates.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

- not being required to comply with the auditor attestation requirements on the effectiveness of our internal controls over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis);
- reduced disclosure obligations regarding executive compensation arrangements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

Corporate Information

We were formed under the laws of the State of Delaware in June 2016 under the name Arcutis, Inc. and changed our name to Arcutis Biotherapeutics, Inc. in October 2019. Our principal executive offices are located at 2945 Townsgate Road, Suite 110, Westlake Village, California 91361, and our telephone number is (805) 418-5006. Our website address is www.arcutis.com. The information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

THE OFFERING

Common stock offered	shares
Option to purchase additional shares	shares
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares in full), based upon the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund the further development of ARQ-151, ARQ-154 and ARQ-252, for working capital and general corporate purposes. See the section entitled “Use of Proceeds.”
Risk factors	You should read the section entitled “Risk Factors” in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed Nasdaq Global Select Market symbol	“ARQT”

The number of shares of our common stock to be outstanding after this offering is based on 54,522,960 shares of our common stock outstanding as of September 30, 2019, including 1,777,301 shares of unvested common stock subject to repurchase, assuming the conversion of all our outstanding shares of convertible preferred stock, including 16,251,628 shares of Series C convertible preferred stock issued in October 2019, into an aggregate of 48,787,895 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 3,147,770 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2019 under our 2017 Equity Incentive Plan, with an average exercise price of $0.80 per share;
- shares of common stock issuable upon the exercise of options outstanding that were granted after September 30, 2019 under our 2017 Equity Incentive Plan, with an average exercise price of $ per share;
- 2,191,014 shares of common stock reserved for future issuance under our 2017 Equity Incentive Plan as of September 30, 2019, which will cease to be available for issuance at the time that our 2020 Equity Incentive Plan becomes effective;
- 2,823,831 additional shares of common stock reserved for future issuance under our 2017 Equity Incentive Plan after September 30, 2019 in connection with the sale of Series C

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

convertible preferred stock in October 2019, which will cease to be available for issuance at the time that our 2020 Equity Incentive Plan becomes effective;

- shares of common stock that will become available for future issuance under our 2020 Equity Incentive Plan upon the effectiveness of the registration statement of which this prospectus forms a part; and shares of common stock that will become available for future issuance under our 2020 Employee Stock Purchase Plan upon the effectiveness of the registration statement of which this prospectus forms a part. Upon completion of this offering, any remaining shares available for issuance under our 2017 Equity Incentive Plan will be added to the shares reserved under our 2020 Equity Incentive Plan and we will cease granting awards under our 2017 Equity Incentive Plan. Our 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan also provide for automatic annual increases in the number of shares reserved under the plans each year, as more fully described in "Executive Compensation—Equity Compensation Plans and Other Benefit Plans."

Except as otherwise indicated, all information in this prospectus reflects or assumes the following:

- the effectiveness of our restated certificate of incorporation and restated bylaws in connection with the completion of this offering;
- the conversion of all of our outstanding shares of convertible preferred stock, including 16,251,628 shares of Series C convertible preferred stock issued in October 2019, into an aggregate of 48,787,895 shares of common stock immediately prior to completion of this offering;
- a -for- reverse stock split, which will become effective prior to the completion of this offering;
- no exercise of outstanding options after September 30, 2019; and
- no exercise of the underwriters' option to purchase additional shares of our common stock in this offering.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

SUMMARY FINANCIAL DATA

The following tables set forth our summary statements of operations and balance sheet data. The summary statements of operations data for the years ended December 31, 2017 and 2018 have been derived from our audited financial statements and related notes thereto included elsewhere in this prospectus. We have derived the summary statements of operations data for the nine months ended September 30, 2018 and 2019, and the summary balance sheet data as of September 30, 2019, from our unaudited interim condensed financial statements and related notes thereto included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles on the same basis as our audited annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal, recurring adjustments, that are necessary for the fair statement of our financial position as of September 30, 2019 and our results of operations for the nine months ended September 30, 2018 and 2019. The following summary financial data should be read in conjunction with "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period. The summary financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Nine Months Ended September 30,	
	2017	2018	2018	2019
			(unaudited)	
	(in thousands, except share and per share data)			
Statements of operations data:				
Operating expenses:				
Research and development	$ 3,411	$ 17,940	$ 12,593	$ 25,765
General and administrative	695	1,795	1,189	4,373
Total operating expenses	4,106	19,735	13,782	30,138
Loss from operations	(4,106)	(19,735)	(13,782)	(30,138)
Other income (expense), net	(872)	480	128	710
Net loss	$ (4,978)	$ (19,255)	$ (13,654)	$ (29,428)
Net loss per share, basic and diluted(1)	$ (3.58)	$ (7.76)	$ (5.92)	$ (8.30)
Weighted-average shares used in computing net loss per share, basic and diluted(1)	1,391,097	2,480,246	2,305,932	3,547,292
Pro forma net loss per share, basic and diluted (unaudited)(1)		$		$
Weighted-average shares used in computing pro forma net loss per share, basic and diluted (unaudited)(1)				

(1) See Notes 2, 11 and 12 to our audited financial statements and Notes 2, 10 and 11 to our unaudited interim condensed financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per share and basic and diluted pro forma net loss per share, and the weighted-average number of shares used in the computation of these per share amounts.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

The table below presents our balance sheet data as of September 30, 2019:

- on an actual basis;
- on a pro forma basis to give effect to: (i) the issuance of 16,251,628 shares of Series C convertible preferred stock for gross cash proceeds of $94.5 million in October 2019 and (ii) the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 48,787,895 shares of our common stock, which includes our Series C convertible preferred stock issued in October 2019, immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis, giving effect to: (i) the pro forma adjustments set forth above and (ii) our receipt of estimated net proceeds from the sale and issuance of shares of our common stock in this offering at an assumed initial public offering price of per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	As of September 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
		(unaudited) (in thousands)	
Balance sheet data:			
Cash, cash equivalents and marketable securities	$ 25,177	$	$
Working capital(2)	19,172		
Total assets	28,303		
Convertible preferred stock	72,252		
Accumulated deficit	(53,704)		
Total stockholders' (deficit) equity	(52,950)		

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by $ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares offered by us in this offering would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by $ million, assuming the initial offering price remains the same and after deducting estimated underwriting discounts commissions and estimated offering expenses payable by us.

(2) We define working capital as current assets less current liabilities. See our audited financial statements and related notes and unaudited interim condensed financial statements and related notes appearing at the end of this prospectus for further details regarding our current assets and current liabilities.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and we have incurred significant losses since our inception. We anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have no products approved for commercial sale and have not generated any revenue from product sales and have incurred losses in each year since our inception in June 2016. We have a limited operating history upon which you can evaluate our business and prospects, and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying potential product candidates, establishing licensing arrangements, undertaking various research and preclinical studies and conducting clinical trials for our product candidates.

We have never generated any revenue from product sales and have incurred losses in each year since our inception in June 2016. We have not yet demonstrated our ability to successfully complete later-stage clinical trials, obtain regulatory approvals, manufacture a drug on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization.

Our net loss for the years ended December 31, 2017 and 2018 was approximately $5.0 million and $19.3 million, respectively, and for the nine months ended September 30, 2018 and 2019 was approximately $13.7 million and $29.4 million, respectively. As of September 30, 2019, we had an accumulated deficit of $53.7 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. We may never achieve profitability and, even if we do, we may not be able to sustain profitability in subsequent periods. We will continue to incur significant research and development and other expenses related to our ongoing operations and the development of our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Even if this offering is successful, we will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

Since our inception, we have invested substantially all of our efforts and financial resources in research and development activities, and we expect to continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates, ARQ-151, ARQ-154, ARQ-252 and ARQ-255, the development or acquisition of additional product candidates and the maintenance and expansion of our business operations and capabilities. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and securing manufacturing and supply of product candidates, and marketing and selling any products approved for sale. These expenditures may also include costs associated with in-licensing dermatology assets consistent with our core strategy. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our lead product candidates and any future product candidates.

As of September 30, 2019, we had capital resources consisting of cash, cash equivalents and marketable securities of $25.2 million. We raised an additional $94.5 million in gross cash proceeds from the sale of Series C convertible preferred stock in October 2019. Based on our planned operations, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least 12 months after the date that our financial statements were issued without raising additional capital. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our planned Phase 3 studies of ARQ-151 in plaque psoriasis, our planned Phase 2b studies of ARQ-154 in scalp psoriasis and seborrheic dermatitis, our planned Phase 2b study of ARQ-252 in hand eczema, our planned Phase 2a study of ARQ-252 in vitiligo and our formulation and preclinical efforts for ARQ-255 in alopecia areata;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost of manufacturing our product candidates and any products we commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of building a sales force in anticipation of product commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;

- the timing and amount of milestone payments due to AstraZeneca, Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, or any future collaboration or licensing partners upon the achievement of negotiated milestones;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products, if any.

Adequate additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis or on attractive terms, we may be required to reduce our workforce, delay, limit, reduce or terminate our research and development activities, preclinical studies, clinical trials or other development activities and future commercialization efforts, or grant rights to develop and market product candidates, such as ARQ-151, that we would otherwise develop and market ourselves.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our future operating results to fall below expectations.

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Furthermore, our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development, or failure to obtain such approvals;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on U.S. Food and Drug Administration, or FDA, guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies, which may include obligations to make significant upfront and milestone payments;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;

- our dependency on CROs and third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates both within and outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements with respect to our product candidates;
- our ability to maintain and enforce our intellectual property position;
- costs related to and outcomes of potential litigation or other disputes in respect of our product candidates and our business;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Our estimated market opportunities for our product candidates are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited.

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot assure you of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this prospectus. If this third-party or internally generated data prove to be inaccurate or we make errors in our assumptions based on that data, our actual market may be more limited than our estimates. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business. The estimates of our market opportunities included in this prospectus should not be taken as indicative of our ability to grow our business. For more information regarding the estimates of market opportunities and the forecasts included in this prospectus, see the sections titled "Market and Industry Data", "Business—ARQ-151—Our Market Opportunity" and "Business—ARQ-154—Our Market Opportunity."

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Risks Related to Development and Commercialization

Our business is dependent on the development, regulatory approval and commercialization of our current product candidates.

We currently have no products that are approved for commercial sale. Our current portfolio includes our lead product candidate ARQ-151, a potent PDE4 inhibitor topical cream for the treatment of plaque psoriasis and atopic dermatitis, and our additional product candidates ARQ-154, a topical foam formulation of ARQ-151 for the treatment of scalp psoriasis and seborrheic dermatitis, and ARQ-252, a potent and highly selective topical JAK1 inhibitor for the treatment of hand eczema. We currently do not have a drug discovery or research and development effort to discover new product candidates, and we have no intention to develop one. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of these current product candidates. We expect to conduct most of our clinical trials in the United States and Canada, with current limited plans for clinical trials in Australia and the European Union. We currently anticipate seeking regulatory approvals in the United States and Canada, but may in the future be subject to additional foreign regulatory authorities and may out-license our product candidates or approved products, if any, in additional foreign markets. In the future, we may also become dependent on other product candidates that we may acquire or in-license. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our lead product candidates or any future product candidates or approved products, if any;
- the willingness of physicians and patients to utilize or adopt our product candidates;
- the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates to remain in good standing with relevant regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

Furthermore, because each of our product candidates targets one or more indications in the medical dermatology field, if any of our product candidates encounter safety or efficacy problems, developmental delays, regulatory issues, supply issues, or other problems, our development plans for the affected product candidate and some or all of our other product candidates could be significantly harmed, which would harm our business. Further, competitors who are developing products in the dermatology field or that target the same indications as us with products that have a similar mechanism of action may experience problems with their products that could indicate or result in class-wide problems or additional requirements that would potentially harm our business.

The factors outlined above, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. For example, we plan to develop ARQ-154, including initiating Phase 2b clinical trials of ARQ-154 in patients with seborrheic dermatitis and in patients with scalp psoriasis, based on our clinical experience with ARQ-151 in psoriasis. Despite our observations of ARQ-151 in a similar dermatological indication, ARQ-154 may not demonstrate comparable results in seborrheic dermatitis or scalp psoriasis. In addition, given its different formulation there is a risk that we select an incorrect dose for ARQ-154, as the clinical effect of ARQ-154 may differ from ARQ-151 at a similar dosing level or we may observe unexpected side effects not previously observed with ARQ-151.

We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

To gain approval to market our product candidates, we must provide the FDA and foreign regulatory authorities with preclinical and clinical data that adequately demonstrate the safety and

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PURSUANT TO 17 C.F.R. SECTION 200.83**

efficacy of the product for the intended indication applied for in the applicable regulatory filing. Product development is long, expensive and uncertain processes, and delay or failure can occur at any stage of any of our preclinical and clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical or clinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

Our lead product candidate ARQ-151, and ARQ-154, its foam formulation, are currently in clinical development. Our product candidate ARQ-252 will soon enter clinical development for hand eczema and vitiligo. ARQ-255 is in formulation and preclinical development for the potential treatment of alopecia areata. We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize our lead product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions, including pricing approval in the European Union.

The FDA or any foreign regulatory authorities can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates is safe and effective for the requested indication;
- the FDA or other relevant foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our proposed Phase 3 clinical trials of ARQ-151 for the treatment of plaque psoriasis;
- the FDA or other relevant foreign regulatory authorities may not find the data from preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products candidates outweigh their safety risks or that there is an acceptable risk-benefit profile;
- the results of our clinical trials may not meet the level of statistical significance or clinical meaningfulness required by the FDA or other relevant foreign regulatory authorities for marketing approval;
- the FDA's or the applicable foreign regulatory authority's requirement for additional preclinical studies or clinical trials which would increase our costs and prolong our development timelines;
- the FDA or other relevant foreign regulatory authorities may disagree with our interpretation of data or significance of results from the preclinical studies and clinical trials of any product candidate, or may require that we conduct additional studies;
- the FDA or other relevant foreign regulatory authorities may not accept data generated from our clinical trial sites;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact our clinical trials and ability to obtain market approvals;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant foreign regulatory authority, as the case may be, may have difficulties scheduling an

advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant foreign regulatory authority, as the case may be, require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA or other relevant foreign regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant foreign regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant foreign regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates;
- the FDA or other relevant foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant foreign regulatory authorities may change their approval policies or adopt new regulations.
- the FDA's or the applicable foreign regulatory authority's non-approval of the formulation, dosing, labeling or specifications;
- the FDA's or the applicable foreign regulatory authority's failure to approve the manufacturing processes of third-party manufacturers upon which we rely or the failure of the facilities of our third-party manufacturers to maintain a compliance status acceptable to the FDA or the applicable foreign regulatory authority; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval from the FDA or applicable foreign agencies for any of our product candidates, the FDA or the applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or the applicable foreign regulatory authority also may approve our lead product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory authority, may not approve our product candidates with the labeling that we believe is necessary or desirable, or may approve them with labeling that includes warnings or precautions or limitations of use that may not be desirable, for the successful commercialization of such product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

Interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our

analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Certain of the endpoints in our planned clinical trials rely on a subjective assessment of the effect of the product candidate in the subject by either the physician or patient, and may prove difficult to meet in patients with more severe disease, which exposes us to a variety of risks for the successful completion of our clinical trials.

Certain of our primary and secondary endpoints in our clinical trials, including our planned Phase 3 clinical trial of ARQ-151 in plaque psoriasis, involve subjective assessments by physician and patients, which can increase the uncertainty of clinical trial outcomes. For example, one of the secondary endpoints requires patients to report pruritus (itching) as measured by the Worst Itch – Numeric Rating Scale and complete or deliver patient or caregiver reported outcomes over the course of our clinical trials. This and other assessments are inherently subjective, which can increase the variability of clinical results across clinical trials and create a significant degree of uncertainty in determining overall clinical benefit. Such assessments can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular patient, and from patient-to-patient and site-to-site within a clinical trial. In addition, frequent reporting requirements may lead to rating fatigue and a loss of accuracy and reliability of the data resulting from our clinical trials. Further, the FDA or comparable foreign regulatory authority may not accept such patient or caregiver reported outcomes as sufficiently validated. Accordingly, these subjective assessments can complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement and generally adversely impact a clinical development program by introducing additional uncertainties.

Patient reported outcome instruments, their use in our Phase 3 clinical trial of ARQ-151 and the inclusion of such data in the product labeling will depend on, but is not limited to, the FDA's review of the following:

- the relevance and importance of the concept(s) of interest to the target patient population;

- the strengths and limitations of the instrument within the given context of use;
- the design and conduct of the trials;
- the adequacy of the submitted data, for example, rigorous data collection and methods to handle missing data; and
- the magnitude of the statistically significant treatment effect should be meaningful to patients.

Further, different results may be achieved depending upon the characteristics of the population enrolled in our studies and which analysis population is used to analyze results. For example, the primary endpoint in our Phase 3 clinical trials of ARQ-151 in plaque psoriasis is based on the percentage of patients achieving a score of "clear" or "almost clear" plus at least a 2-grade improvement from baseline on the 5 point Investigator's Global Assessment (or IGA) scale, referred to as "IGA Success". Success in our Phase 3 clinical trials, or other clinical trials with these or similar endpoints, requires the enrollment of patients with conditions that are severe enough to facilitate a two-grade improvement in the IGA scale, but not so severe that they cannot achieve a "clear" or "almost clear" in IGA score in light of the severity of their disease. It is therefore possible that we enroll patients with conditions so severe that they do not or are unable to realize an IGA of 0 (clear) or 1 (almost clear) during the period covered by the clinical trial. As a result, there is no guarantee that our Phase 3 clinical trials, if commenced, will produce the same statistically significant results in "IGA Success", which will serve as the primary endpoint, as our Phase 2b clinical trial, and there can be no guarantee that the characteristics of the population enrolled in our Phase 3 clinical trials does not adversely impact the results reported for such trial, any of which could have an adverse effect on our ability to secure regulatory approval for our product candidates.

Enrollment and retention of subjects in clinical trials is expensive and time consuming and may result in additional costs and delays in our product development activities, or in the failure of such activities.

We may not be able to initiate or continue clinical trials for ARQ-151 or our other product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as ARQ-151, ARQ-154, ARQ-252 and ARQ-255, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the selection of the patient population required for analysis of the trial's primary endpoints;
- the eligibility criteria for the study in question;
- the frequency and extent of clinical trial site visits and study assessments;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Furthermore, any negative results that we may report in preclinical studies or clinical trials of our product candidates may make it difficult or impossible to recruit and retain subjects in other clinical trials of that same or any similar product candidate. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and impede our ability to obtain additional financing.

Serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

As we continue our development of our product candidates and initiate additional preclinical studies or clinical trials of these or future product candidates, if any, serious adverse events, unacceptable levels of toxicity, undesirable side effects or unexpected characteristics may emerge, causing us to abandon these product candidates or limit their development to more narrow uses, lower potency levels or subpopulations in which the serious adverse events, unacceptable levels of toxicity, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective.

If our product candidates are associated with adverse effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development, institute burdensome monitoring programs, or limit development to more narrow uses or lower or less frequent dosing in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board, or similar regulatory authorities outside the United States, may also require that we suspend, discontinue, or limit our clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the labels;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy, or REMS;
- we may be required to conduct Phase 4 clinical trials as postmarketing requirements, or PMRs;
- we could be sued and held liable for harm caused to patients; and
- our reputation and physician or patient acceptance of our products may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

As a company, we have never completed a Phase 3 program or obtained marketing approval for any product candidate and we may be unable to successfully do so in a timely manner, if at all, for any of our product candidates.

Conducting a Phase 3 clinical trial and preparing, and obtaining marketing approval for, a product candidate is a complicated process. Although members of our management team have participated in pivotal trials and obtained marketing approvals for product candidates in the past while employed at other companies, we as a company have not done so. As a result, these activities may require more time and cost more than we anticipate, and we may be unable to successfully complete them for any of our product candidates.

To date, we have completed two Phase 2 studies of ARQ-151 in plaque psoriasis and intend to initiate a Phase 3 program, which will include two registrational Phase 3 studies in plaque psoriasis. We also anticipate commencing more advanced clinical trials of ARQ-151 in the treatment of atopic dermatitis after the completion of our ongoing Phase 2a clinical trial in atopic dermatitis. Failure to successfully complete, or delays in, our pivotal trials or related regulatory submissions would prevent us from or delay us in obtaining regulatory approval for our product candidates. In addition, it is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our applications that they are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept our applications or issue marketing authorizations for our product candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA for any other applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Additionally, similar risks could apply to receipt of marketing authorizations by comparable regulatory authorities in foreign jurisdictions.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if our lead product candidate or our other product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our lead product candidate or our other product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate adequate product revenue or become profitable. The degree of market acceptance of a product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the safety, efficacy, risk-benefit profile and potential advantages compared to alternative or existing treatments, such as steroids topical treatments, oral treatments, and biologic injections for the treatment of psoriasis, which physicians may perceive to be adequately effective for some or all patients;
- side effects that may be attributable to our product candidates and the difficulty of or costs associated with resolving such side effects;
- limitations or warnings contained in the labeling approved for our product candidates by FDA or other applicable foreign regulatory authorities;

- any restrictions on the use of our products, and the prevalence and severity of any side effects;
- the content of the approved product label;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments and over-the-counter, or OTC treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies over existing therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement at any given price level of each of our product candidates;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of any of our product candidates.

We cannot assure you that our current or future product candidates, if approved, will achieve market acceptance among physicians, patients, third-party payors or others in the medical community necessary for commercial success. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would harm our results of operations.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development or commercialization of any of our products or product candidates for a variety of reasons, including the appearance of new technologies that render our product obsolete, competition from a competing product or changes in or inability to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

As to any of our product candidates that become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our prescription-only products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for certain of our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies.

Further, third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions in both the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

We currently have no sales, marketing or distribution capabilities and have no experience as a company in commercializing products.

To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization. We do not currently have any infrastructure for the sales, marketing, or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

We currently expect to build a dermatologist-focused sales, distribution and marketing infrastructure to market our product candidates in North America, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact its commercialization. If the commercial launch of any of our product candidates, if approved, for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

If we seek to market any products in our pipeline in countries other than the United States, we will need to comply with the regulations of each country in which we seek to market our products.

None of our product candidates are currently approved for sale by any government authority in any jurisdiction. If we fail to comply with regulatory requirements in any market we decide to enter, or to obtain and maintain required approvals, or if regulatory approvals in the relevant markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Marketing approval in one jurisdiction, including the United States, does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory process in others. Failure to obtain a marketing approval in countries in which we seek to market our products or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for any of our products.

Our license agreements obligate us to make certain milestone payments, some of which will be triggered prior to our commercialization of any of our product candidates.

Certain of the milestone payments payable by us to AstraZeneca and Hengrui, are due upon events that will occur prior to our planned commercialization of the applicable product candidates. Accordingly, we will be required to make such payments prior to the time at which we are able to generate revenue, if any, from sales of any of our product candidates, if approved.

For example, upon regulatory approval from the FDA to commercialize ARQ-151 in the United States, but prior to commencement of commercialization or sales of ARQ-151, we will be required to make certain milestone payments to AstraZeneca. We have agreed to make cash payments to AstraZeneca of up to an aggregate of $14.5 million upon the achievement of specified clinical development and regulatory approval milestones with respect to products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, AZ-Licensed Products, and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country.

If we exercise our exclusive option, we will pay Hengrui an additional $1.5 million option exercise cash payment. In addition, if exercised, we have agreed to make cash payments of up to an aggregate of $20.5 million upon our achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional $200.0 million in sales-based milestones based on achieving certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products we commercialize under the agreement, we will pay tiered royalties to Hengrui on net sales of each licensed product by us, or our affiliates, or our sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the later of (1) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, we are obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income we receive from sublicensees of our rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. Furthermore, if we are forced to raise additional funds, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves. If we are unable to raise additional funds or maintain sufficient liquidity to make our payment obligations if and when they become due, including payment obligations under the license agreement with AstraZeneca and, if we exercise our option thereunder, under the option and license agreement with Hengrui, we may be in material breach of our agreements and our counterparties may seek legal action or remedies against us (including by seeking to terminate the relevant agreements), which would harm our business, financial condition, results of operations and prospects.

We face significant competition from other biotechnology and pharmaceutical companies targeting medical dermatological indications, and our operating results will suffer if we fail to compete effectively.

The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for our targeted inflammatory and medical dermatological indications. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies or drugs that become available in the future for the treatment of our target indications. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Even if another branded or generic product or OTC product is less effective than our product candidates, a less effective branded, generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience.

Certain of our product candidates, if approved, will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies to gain a share of some patients' discretionary budgets and for physicians' attention within their clinical practices. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

We are aware of several companies that are working to develop drugs that would compete against our product candidates for the treatment of psoriasis, atopic dermatitis, hand eczema, vitiligo and alopecia areata.

For psoriasis, our primary competitors include injected biologic therapies such as Humira, marketed by AbbVie Inc. and Eisai Co., Ltd., and Enbrel, marketed by Amgen Inc., Pfizer Inc., and Takeda Pharmaceutical Company Limited; non-injectable systemic therapies used to treat plaque psoriasis such as Otezla, marketed by Celgene Corporation; topical therapies such as branded and generic versions of clobetasol, such as Clobex, marketed by Galderma Laboratories, LP; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat psoriasis and compete with ARQ-151, including tapinarof, under development by Dermavant Sciences, Inc., and SNA-120, under development by Sienna Biosciences, Inc.

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For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., and generic and branded versions of low to mid-potency steroids such as hydrocortisone and betamethasone; and the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with ARQ-151, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc., oral PF-04965842, under development by Pfizer Inc., oral upatacitinib, under development by AbbVie, Inc. and injectable lebrikizumab, under development by Dermira, Inc.

For hand eczema, our primary competitors include topical therapies such as branded and generic versions of clobetasol, such as Clobex, and generic versions of betamethasone dipropionate. The only other prescription product candidate we are aware of under development for the treatment of hand eczema that would compete with ARQ-252 is delgocitinib.

For vitiligo, our primary competitors include topical therapies such as generic and branded versions of calcineurin inhibitors, including Elidel, marketed by Bausch Health; branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat vitiligo and compete with ARQ-252, including but not limited to: topical cerdulatinib, under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, and both PF-06651600 and PF06700841, under development by Pfizer Inc.

For alopecia areata, our primary competitors include topical therapies such as branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; intralesional corticosteroid injections such as branded and generic versions of triamcinolone, including Kenalog, marketed by Bristol-Myers Squib; and systemic immunosuppressants including generic versions of systemic steroids such as prednisone, branded and generic versions of cyclosporine, including Sandimmune, marketed by Sandoz, and branded systemic JAK inhibitors, including Xeljanz, marketed by Pfizer, Inc. In addition, there are several prescription product candidates under development that could potentially be used to treat alopecia areata and compete with ARQ-255, including but not limited to: PF-06651600, under development by Pfizer, Inc., CTP-543, under development by Concert Pharmaceuticals, and baricitinib, under development by Eli Lilly and Company.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner

in which they can market their products. As a result, we expect to face more competition in these markets than in the United States.

Our ability to compete successfully will depend largely on our ability to:

- develop and commercialize therapies that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our technologies and product;
- obtain required regulatory approvals, including approvals to market our product candidates in ways that are differentiated from existing and future therapies and OTC products and treatments;
- successfully commercialize our product candidates, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapies.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs or OTC treatments would have an adverse impact on our business, financial condition and prospects.

Risks Related to Our Business and Operations

We will need to increase the size of our organization, and we may experience difficulties in executing our growth strategy and managing any growth.

As of November 12, 2019, we had 27 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our lead product candidates or any future product candidates.

Our management and personnel, systems and facilities currently in place are not adequate to support our future growth. In order to effectively execute our growth strategy, we will need to identify, recruit, retain, incentivize and integrate additional employees in order to expand our ability to:

- manage our clinical trials effectively;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties;
- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates effectively and in a cost-effective manner;
- establish and maintain relationships with development and commercialization partners; and

- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels.

If we are unable to successfully identify, recruit, retain, incentivize and integrate additional employees and otherwise expand our managerial, operational, finance and other resources, our business and operational performance will be materially and adversely affected.

If we are not successful in acquiring, developing, and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on the continued preclinical and clinical testing and potential approval of our current product candidates, a key element of our strategy is to acquire, develop and commercialize a diverse portfolio of product candidates to serve the dermatology market. We do not currently intend to conduct drug discovery or research and development efforts to discover new product candidates, but rather we intend to acquire or in-license rights to existing molecules to develop for dermatological indications. In addition, while we believe that our strategy allows us to move more rapidly through clinical development and at a potentially lower cost, we may be unable to progress product candidates more quickly or at a lower cost.

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by patents or other proprietary rights controlled by third parties;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

In the event we seek to identify and acquire or in-license additional product candidates in the dermatology field, our process for doing so may be slow and may ultimately be unsuccessful for a number of reasons, including those discussed in these risk factors and also:

- potential product candidates may, upon further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases; or
- the acquisition or in-licensing transactions can entail numerous operational and functional risks, including exposure to unknown liabilities, disruption of our business, or incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, or higher than expected acquisition or integration costs.

We may choose to focus our efforts and resources on an in-licensing or acquiring a potential product candidate that ultimately proves to be unsuccessful. We also cannot be certain that, following an acquisition or in-licensing transaction, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to identify and acquire suitable product candidates for clinical development, this would adversely impact our business strategy, our financial position and share price.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize future product candidates.

We may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us. Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Furthermore, we cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop our current and any future product candidates, commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including our Chief Executive Officer, Todd Franklin Watanabe and our Chief Technical Officer, David W. Osborne, Ph.D. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our products or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and

other businesses, particularly in the Northern Los Angeles Area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future product candidates we develop. Although we currently carry product liability insurance covering our clinical trials, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which

we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

We will incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We will incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

After this offering, we will be subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

In addition, we expect that we will need to implement an enterprise resource planning, or ERP, system for our company. An ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. However, an ERP system would likely

require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Additionally, during the conversion process, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in implementing or using an ERP system could adversely affect our controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm to our business.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the Northern Los Angeles Area, which in the past has experienced both severe earthquakes and wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and

business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, our third-party manufacturers or suppliers are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

We depend on our information technology systems, and any failure of these systems, or those of our CROs or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber-attacks, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations, financial condition and prospects.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or

litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Our future commercial partners, as well as our employees and independent contractors, including principal investigators, consultants, suppliers, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our future commercial partners, as well as our employees and independent contractors, including principal investigators, consultants, suppliers, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such foreign regulatory authorities; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Risks Related to Our Reliance on Third Parties

We currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. The loss of these manufacturers, or their failure to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not currently have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. Instead, we currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate.

We and the manufacturers of our products rely on suppliers of raw materials used in the production of our products. Some of these materials are available from only one source. Additionally, we have not yet engaged any manufacturer for the commercial supply of our product candidates. Although we intend to enter into such agreements prior to commercial launch of any of our product candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial manufacture of our product candidates, we will have no other means of producing our lead product candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturer's facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

Furthermore, there are a limited number of suppliers for materials we use in our product candidates, which exposes us to the risk of disruption in the supply of the materials necessary to manufacture our product candidates for our preclinical studies and clinical trials, and if approved, ultimately for commercial sale. In the case of ARQ-252 and ARQ-255, we have an agreement with Hengrui for the supply of SHR0302 API for preclinical studies and clinical trials. We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. In addition, any significant delay in, or quality control problems with respect to, the supply of a product candidate, or the raw material components thereof, for an ongoing study or trial could considerably delay completion of our preclinical studies or clinical trials, product testing and potential regulatory approval of our product candidates.

In addition, to manufacture our product candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers may need to increase

manufacturing capacity and, in some cases, we plan to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the commercial launch of our lead product candidates or any future product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved.

The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

If our third-party manufacturers fail to comply with manufacturing or other regulations, our financial results and financial condition will be adversely affected.

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture or our product candidates.

Before beginning commercial manufacture of ARQ-151, ARQ-154, ARQ-252 or ARQ-255, the process and systems used in the manufacture of ARQ-151, ARQ-154, ARQ-252 or ARQ-255 must be approved and each facility must have a compliance status that is acceptable to the FDA and other regulatory authorities. In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and foreign regulatory authorities, before and after product approval. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to continue to pass or initially pass federal, state or international regulatory inspections. Furthermore, although we do not have day-to-day control over the operations of our contract manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

If a third-party manufacturer with whom we contract is unable to comply with applicable laws and regulations, including cGMPs, ARQ-151, ARQ-154, ARQ-252 or ARQ-255 may not be approved, or we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize ARQ-151, ARQ-154, ARQ-252, ARQ-255 or any future product candidates.

We do not have the ability to independently conduct non-clinical studies and clinical trials. We rely on third parties, such as CROs, to conduct preclinical studies and clinical trials of ARQ-151, ARQ-154, ARQ-252 and ARQ-255. The third parties with whom we contract for execution of our preclinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. These third parties may also have relationships with other

commercial entities, some of which may compete with us. In some cases, these third parties could terminate their agreements with us without cause.

Although we rely on third parties to conduct our preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, including some regulations commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that appropriate human subjects protections are in place, including that the trial subjects are adequately informed of the potential risks and other consequences of participating in clinical trials.

In addition, the execution of non-clinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated, which would have a material adverse effect on our business.

Risks Related to Intellectual Property

We may not be able to obtain, maintain or enforce patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates and technologies will depend in part on our and our licensors' ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing upon our proprietary rights. Our ability to protect any of our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

Our patent portfolio includes patents and patent applications in the United States and foreign jurisdictions where we believe there is a market opportunity for our products. The covered technology and the scope of coverage vary from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our technologies. Any patents that we may obtain may be narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents, third parties may be able to make, use or sell products identical to or substantially similar to, our product candidates.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current licensors, or any future licensors or licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted, and as a result may not be able to be enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the

preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how to our processes, methods, and know-how which we consider our trade secrets. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our and our licensor's ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under our existing patents or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even with respect to our patents that have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any, over such aspects of our technology. Even if patents do successfully issue covering such aspects of our technology, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we own or license respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidates. Even if the patent applications that we own or license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drugs in a non-infringing manner.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in

protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- for some product candidates, including ARQ-151 and ARQ-154, we expect that composition of matter patent protection for the active pharmaceutical ingredient will not be available at the time we expect to commercialize, and we will therefore need to rely on formulation, method of use and other forms of claims for patent protection;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. Our issued U.S. patents relating to ARQ-151 and ARQ-154 with claims directed to, among other things, formulating roflumilast in combination with hexylene glycol are currently projected to expire on June 7, 2037 and the issued U.S. patents which we have exclusive option rights to from Hengrui related to the composition of matter of the active ingredient in ARQ-252 and ARQ-255 (orbisulfate or crystal forms thereof) are currently projected to expire between January 21, 2033 and December 1, 2035 unless a patent term extension is granted. Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented

know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of ARQ-151, ARQ-154, ARQ-252, ARQ-255 or any future product candidates.

There have been many lawsuits and other proceedings asserting patents and other intellectual property rights in the pharmaceutical and biotechnology industries. We cannot assure you that our exploitation of ARQ-151, ARQ-154, ARQ-252 or ARQ-255 will not infringe existing or future third-party patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing ARQ-151, ARQ-154, ARQ-252 or ARQ-255. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. We may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of ARQ-151, ARQ-154, ARQ-252 or ARQ-255.

We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. We may be required to indemnify future collaborators against such claims. If a patent infringement suit were brought against us or our future collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights obtained may be nonexclusive, which would not confer a competitive advantage to us from an exclusivity perspective. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms to necessary third party patent rights. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office, or the USPTO, to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

We may be subject to claims by third parties asserting that we, our employees or our licensors have misappropriated their intellectual property, including trade secrets, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensor's employees were previously employed at other biotechnology or pharmaceutical companies. Although we and our licensors try to ensure that our

employees and our licensor's employees do not use the proprietary information or know-how of others in their work for us, including by contract, we or our licensors may be subject to claims that these employees, our licensors or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may in the future be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensor fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we and our licensor are successful in prosecuting or defending against such claims, litigation could result in substantial costs.

The validity, scope and enforceability of any patents listed in the Orange Book that cover ARQ-151, ARQ-154, ARQ-252 or ARQ-255 can be challenged by competitors.

If ARQ-151, ARQ-154, ARQ-252 or ARQ-255 is approved by the FDA, one or more third parties may challenge the patents covering ARQ-151, ARQ-154, ARQ-252 or ARQ-255, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an abbreviated new drug application, or ANDA, for a generic drug bioequivalent to ARQ-151, ARQ-154, ARQ-252 or ARQ-255, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term for our product candidates, our business may be materially harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology,

product candidates and our target indications. Our issued U.S. patents, with claims directed to roflumilast formulations with reduced crystal growth, encompassing ARQ-151, are currently projected to expire on June 7, 2037. Certain issued U.S. patents that we have licensed from Hengrui relating to, among other things, treatment of several diseases or disorders, including various cancers, allograft rejection, graft versus host disease, rheumatoid arthritis, atopic dermatitis, and psoriasis with SHR0302, or bisulfate and crystal forms thereof, are currently projected to expire beginning in 2033. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of the U.S. patents covering our product candidates may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to only one patent that covers the approved product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may need to license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

Additional third parties, apart from our current licensors, may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of these third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms, in which case our business would be harmed. The risks described

elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could harm our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates, including all of the licensed rights under our exclusive supply and license agreements with AstraZeneca and Hengrui, in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and implemented wide-ranging patent reform legislation, and that legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our

issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications.

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. Having a mandatory non-exclusive license grant may diminish the value of our patents as well as making it more difficult to protect our products.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering any of our product candidates, our competitors might be able to enter the market earlier than anticipated, which would harm our business.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. In addition, third parties may file first for our trademarks in certain countries. If they succeeded in registering such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

We have not yet registered trademarks for a commercial trade name for our lead candidates in the United States or foreign jurisdictions and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for our lead product candidates in the United States or any foreign jurisdiction. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We may not be able to protect our proprietary information and technology adequately. Although we use reasonable efforts to protect our proprietary information, technology, and know-how, our employees, consultants, contractors, outside scientific advisors, licensors or licensees may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our proprietary information, technology or know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect proprietary information, technology, and know-how. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our proprietary information, technology, and know-how. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop similar or equivalent proprietary information, and third parties may otherwise gain access to our proprietary knowledge.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We have licensed or acquired certain intellectual property rights covering our current product candidates from third parties, including AstraZeneca and Hengrui. We are heavily dependent on our

agreements with such third parties for our current product candidates. If, for any reason, one or more of our agreements with such third parties is terminated or we otherwise lose those rights, it could harm our business. Our license and other agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any such material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims or inform and cooperate with our licensors to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of any of our product candidates.

Our commercial success depends in part on our and our licensors avoiding infringement and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other

intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing,

marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely impact our ability to raise additional funds or otherwise harm our business, results of operation, financial condition or cash flows.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could adversely impact the price of our common shares. If securities analysts or investors perceive these results to be negative, it could adversely impact the price of our common shares. The occurrence of any of these events may harm our business, results of operation, financial condition or cash flows.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities, and have a harmful effect on the success of our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could adversely impact the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs, or in-license needed technology or other product candidates. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved.

Risks Related to Government Regulation

Even if we receive regulatory approval of our product candidates, we will be subject to extensive and ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals or other marketing authorizations we obtain for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or the conditions of approval or marketing authorization, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA

may also require a REMS as a condition of approval of our drug product candidates, such as ARQ-151, ARQ-154, ARQ-252 and ARQ-255, which could include requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority authorizes our product candidates for marketing, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to accept new marketing applications or supplements, approve or otherwise authorize for marketing pending applications or supplements to applications filed by us or suspension or revocation of approvals or other marketing authorizations;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current presidential administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the

payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would harm our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could harm our business.

Our product candidates, if authorized for marketing, may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our product candidates, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, if such products are marketed, could have a negative impact on us.

With respect to any of our product candidates in clinical testing or approved by FDA, we will be subject to the FDA's safety reporting requirements. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our approval or delay in approval of future products.

We may choose to voluntarily recall a product if any material deficiency is found. A recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls involving our product candidates, if and when they are approved or otherwise authorized for marketing, could be particularly harmful to our business, financial condition and results of operations.

We may be subject to healthcare laws and regulations relating to our business, and could face substantial penalties if we are determined not to have fully complied with such laws, which would have an adverse impact on our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, customers and patients, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A

person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, (as well as certain other healthcare professionals beginning in 2022) and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members;
- state privacy laws and regulations, such as those of California, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information (for example, in June 2018, California enacted the California Consumer Privacy Act (which will go into effect on January 1, 2020) that gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, and provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation; resulting in increased compliance costs and potential liability);
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign

government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with and/or ownership interests by physicians and other healthcare providers, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

We have conducted and may in the future conduct clinical trials for our product candidates outside the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials.

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States, including in Canada and Europe. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory authorities have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions

where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on the pricing of medical items and services, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The current presidential administration and U.S. Congress have sought and will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, was enacted, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include the Budget Control Act of 2011, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year and will remain in effect through 2027; the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years; and the Medicare Access and CHIP Reauthorization Act of 2015, which, among other things, ended the use of the sustainable growth rate formula and provides for a 0.5% update to physician payment rates for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other foreign regulatory authorities strictly regulate the marketing of and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other foreign regulatory authorities as reflected in the product's approved labeling. In addition, although we believe our product candidates may exhibit a lower risk of side effects or more favorable tolerability profile or better symptomatic improvement than other products for the indications we are studying, without head-to-head data, we will be unable to make comparative claims for our product candidates, if approved. If we receive regulatory approval for any of our products and are found to have promoted any of our products for off-label uses, we may become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our brand and reputation could be damaged. The FDA has also previously requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they determine our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates in ways that fall outside the scope of the approved indications, as he or she may deem appropriate in his or her medical judgment. Physicians may also misuse our product candidates or use improper techniques, which may lead to adverse results, side effects or injury and, potentially, subsequent product liability claims. Furthermore, the use of our product candidates for indications other than those approved by the FDA and/or other regulatory authorities may not effectively treat such conditions, which could harm our brand and reputation among both physicians and patients.

Risks Related to Our Common Stock and This Offering

There has been no established public market for our common stock, the stock price of our common stock may be volatile or may decline and you may not be able to resell your shares at or above the offering price.

Prior to this offering, no market for shares of our common stock existed and an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock will be determined through negotiations with the underwriters and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares

at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- limited daily trading volume resulting in the lack of a liquid market;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- regulatory or legal developments in the United States and foreign countries;
- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;
- the execution of our partnering and manufacturing arrangements;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the success of, and fluctuations in, the commercial sales any product candidates approved for commercialization in the future;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- FDA or foreign regulatory actions affecting us or our industry;
- changes in the structure of healthcare payment systems;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;

- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;
- the size of our market float;
- the expiration of market standoff or contractual lock-up agreements and future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- changes in accounting principles;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed in this prospectus.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We qualify as an "emerging growth company" as defined in the JOBS Act and we have decided to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, including delaying adopting new or revised accounting standards, which could make our common stock less attractive to investors.

We qualify as an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including certain reduced financial statement reporting obligations, reduced disclosure obligations about our executive compensation arrangements, exemptions from the requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements and exemption from the auditor's attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However,

if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase our common stock in this offering, you will incur immediate substantial dilution of approximately $ per share, based on the initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, and our pro forma net tangible book value as of September 30, 2019. In addition, following this offering, purchasers in this offering will have contributed approximately % of the total gross consideration paid by stockholders to us to purchase shares of our common stock, through September 30, 2019, but will own only approximately % of the shares of common stock outstanding immediately after this offering. Furthermore, if the underwriters exercise their option to purchase additional shares, or outstanding options are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

Raising additional funds by issuing securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of a common shareholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization

efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering as of October 10, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 75% of our voting stock and, upon the closing of this offering, that same group will hold approximately % of our outstanding voting stock (inclusive of shares of common stock purchased in this offering and assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options). Therefore, even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Based on shares outstanding as of September 30, 2019, upon completion of this offering, we will have outstanding a total of shares of common stock. Of these shares, only shares of common stock sold in this offering, or shares if the underwriters exercise their option to purchase additional shares in full, will be freely tradable, without restriction, in the public market immediately after this offering. Each of our officers, directors and certain of our stockholders have entered or will enter into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. However, our underwriters may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of September 30, 2019, up to an additional shares of common stock will be eligible for sale in the public market, approximately of which are held by our officers, directors and their affiliated entities, and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, shares of our common stock that are subject to outstanding options as of September 30, 2019 and shares of our common stock that are subject to options granted after September 30, 2019 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act.

After this offering, the holders of an aggregate of shares of our outstanding common stock as of September 30, 2019 will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also intend to register shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to the 180-day lock-up period under the lock-up agreements described above and in the section entitled "Underwriting."

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding warrant or options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We expect to use the net proceeds to us from this offering, together with our existing cash, cash equivalents and marketable securities, to fund further development of our ARQ-151, ARQ-154 and ARQ-252 programs and for working capital and general corporate purposes. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

Our ability to utilize our net operating loss, or NOL, carryforwards and research and development income tax credit carryforwards may be limited.

As of December 31, 2018, we had NOL carryforwards available to reduce future taxable income, if any, for federal and California income tax purposes of $17.2 million and $18.1 million, respectively. If not utilized, California NOL carryforwards will expire beginning in 2036 of the federal NOL carryforwards, $3.5 million originated before the 2018 tax year and will begin to expire in 2036 if not utilized. Under the Tax Act, the remaining $13.6 million of federal NOL carryforwards generated after December 31, 2017 will carryforward indefinitely with utilization limited to 80% of taxable income. As of December 31, 2018, we had federal and California research and development tax credit carryforwards of $751,000 and $261,000, respectively. If not utilized, the federal research and development tax credit carryforwards will begin to expire in 2037. The California research and development tax credit carryforwards are available indefinitely.

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership by certain stockholders over a three year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. A formal study has not been completed to determine if a change in ownership, as defined by Section 382, has occurred. We believe that we may undergo an “ownership change” limitation as a result of this offering (some of which shifts are outside of our control). We may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

Our restated certificate of incorporation and restated bylaws that will be in effect immediately prior to the completion of this offering will contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions will include the following:

- a classified board of directors with three year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of a super-majority of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer or the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. For a description of our capital stock, see the section titled "Description of Capital Stock."

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our restated certificate of incorporation and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our restated bylaws to be effective immediately prior to the completion of this offering and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

In addition, our restated certificate of incorporation, to the fullest extent permitted by law, will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Use of Proceeds,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business” contains forward-looking statements. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- the success, cost and timing of our plans to develop and commercialize immune-dermatology drugs, including our current products, ARQ-151, ARQ-154, ARQ-252 and ARQ-255 for indications including psoriasis, atopic dermatitis, scalp psoriasis, seborrheic dermatitis, hand eczema, vitiligo and alopecia areata;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for ARQ-151, ARQ-154, ARQ-252 and ARQ-255;
- future agreements, if any, with third parties in connection with the commercialization of our product candidates;
- the success, cost and timing of our product candidate development activities and planned clinical trials;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the potential market size and the size of the patient populations for our product candidates, if approved for commercial uses;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key management and technical personnel;
- our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our product candidates;
- our use of the net proceeds from this offering; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk factors” and elsewhere in this prospectus. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot

guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ from the sale of shares of common stock in this offering, or approximately $ if the underwriters exercise their option to purchase additional shares in full, based on an assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares offered by us in this offering would increase (decrease) the net proceeds that we receive from this offering by $ million, assuming the initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash, cash equivalents and marketable securities, as follows:

- approximately $ million to $ million to fund further development of our ARQ-151 programs through Phase 3 in psoriasis and into Phase 2b in atopic dermatitis;
- approximately $ million to $ million to fund further development of our ARQ-154 programs into Phase 3 in seborrheic dermatitis and scalp psoriasis;
- approximately $ million to $ million to fund further development of our ARQ-252 programs into Phase 2b in hand eczema; and
- any remaining amounts to fund working capital and general corporate purposes.

Based on our planned use of the net proceeds, we estimate such funds, together with our existing cash, cash equivalents and marketable securities, will be sufficient for us to fund our operating expenses and capital expenditure requirements through at least .

The expected use of the net proceeds from the offering represents our intentions based upon our current plans and business conditions. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend on a number of factors, including the success of research and product development efforts, cash generated from future operations and actual expenses to operate our business. We may use a portion of the net proceeds for the acquisition of, or investment in, businesses that complement our business, although we have no present commitments or agreements.

The amounts and timing of our preclinical and clinical expenditures and the extent of preclinical and clinical development may vary significantly depending on numerous factors, including the status, results and timing of our current clinical trials and clinical trials which we may commence in the future, the product approval process with the FDA and foreign regulatory authorities, any new collaborations we may enter into with third parties and any unforeseen cash needs. As a result, we cannot predict with any certainty all of the particular uses for the net proceeds or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

The expected net proceeds of this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

Pending the uses described above, we intend to invest the net proceeds from this offering in short term, investment-grade interest-bearing securities such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of September 30, 2019:

- on an actual basis;
- on a pro forma basis to give effect to: (i) the issuance of 16,251,628 shares of Series C convertible preferred stock for gross cash proceeds of $94.5 million in October 2019 and (ii) the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 48,787,895 shares of our common stock, which includes our Series C convertible preferred stock issued in October 2019, immediately prior to the completion of this offering and (iii) the filing and effectiveness of our restated certificate of incorporation, in each case immediately prior to this offering; and
- on a pro forma as adjusted basis, giving effect to: (i) the pro forma adjustments set forth above and (ii) our receipt of estimated net proceeds from the sale and issuance of shares of our common stock in this offering at an assumed initial public offering price of per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The information set forth in the table below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering as determined at pricing. You should read this table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and related notes and unaudited interim condensed financial statements and related notes thereto included elsewhere in this prospectus.

	As of September 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
	(in thousands, except share and per-share data) (unaudited)		
Cash, cash equivalents and marketable securities	$ 25,177	$	$
Convertible preferred stock, $0.0001 par value; 32,536,270 shares authorized, 32,536,267 shares issued and outstanding and aggregate liquidation preference of $71,800, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	$ 72,252	$	$
Stockholders' equity (deficit):			
Preferred stock, $0.0001 par value: no shares authorized, issued or outstanding, actual; shares authorized, no shares issued or outstanding pro forma and pro forma as adjusted	—		
Common stock, $0.0001 par value; 44,000,000 shares authorized, 5,735,065 shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted	—		
Additional paid-in capital	754		
Accumulated other comprehensive income	—		
Accumulated deficit	(53,704)		
Total stockholders' (deficit) equity	(52,950)		
Total capitalization	$ 19,302	$	$

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and marketable securities, additional paid-in-capital, total stockholders' equity and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares offered by us in this offering would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and marketable securities, additional paid-in-capital, total stockholders' equity and total capitalization by approximately $ million, assuming the initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding after this offering is based on 54,522,960 shares of our common stock outstanding as of September 30, 2019, including 1,777,301 shares of unvested common stock subject to repurchase, assuming the conversion of all our outstanding shares of convertible preferred stock, including 16,251,628 shares of Series C convertible preferred stock issued in October 2019, into an aggregate of 48,787,895 shares of our common stock immediately prior to completion of this offering, and excludes:

- 3,147,770 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2019 under our 2017 Equity Incentive Plan, with an average exercise price of $0.80 per share;
- shares of common stock issuable upon the exercise of options outstanding that were granted after September 30, 2019 under our 2017 Equity Incentive Plan, with an average exercise price of $ per share;
- 2,191,014 shares of common stock reserved for future issuance under our 2017 Equity Incentive Plan as of September 30, 2019, which will cease to be available for issuance at the time that our 2020 Equity Incentive Plan becomes effective;
- 2,823,831 additional shares of common stock reserved for future issuance under our 2017 Equity Incentive Plan after September 30, 2019 in connection with the sale of Series C convertible preferred stock in October 2019, which will cease to be available for issuance at the time that our 2020 Equity Incentive Plan becomes effective;
- shares of common stock that will become available for future issuance under our 2020 Equity Incentive Plan upon the effectiveness of the registration statement of which this prospectus forms a part; and shares of common stock that will become available for future issuance under our 2020 Employee Stock Purchase Plan upon the effectiveness of the registration statement of which this prospectus forms a part. Upon completion of this offering, any remaining shares available for issuance under our 2017 Equity Incentive Plan will be added to the shares reserved under our 2020 Equity Incentive Plan and we will cease granting awards under our 2017 Equity Incentive Plan. Our 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan also provide for automatic annual increases in the number of shares reserved under the plans each year, as more fully described in "Executive Compensation—Equity Compensation Plans and Other Benefit Plans."

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after this offering.

Net tangible book value (deficit) per share is determined by dividing our total tangible assets (which excludes deferred offering costs) less our total liabilities and convertible preferred stock by the number of shares of common stock outstanding. Our historical net tangible book value (deficit) as of September 30, 2019 was $(53.0) million, or $(9.23) per share of our common stock, based on 5,735,065 shares of common stock outstanding as of September 30, 2019 including 1,777,301 shares of unvested common stock subject to repurchase.

Our pro forma net tangible book value as of September 30, 2019 was approximately $ million, or $ per share of common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets (which excludes deferred offering costs) reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of September 30, 2019, after giving effect to: (i) the issuance of 16,251,628 shares of Series C convertible preferred stock for gross cash proceeds of $94.5 million in October 2019 and (ii) the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 48,787,895 shares of common stock, which includes our Series C convertible preferred stock issued in October 2019.

After giving effect to (i) the pro forma adjustments set forth above and (ii) our sale in this offering of shares of our common stock at an assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2019 would have been approximately $ million, or $ per share of our common stock. This represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to investors in this offering. Net tangible book value dilution per share to new investors in this offering represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price, per share		$
Historical net tangible book value (deficit) per share as of September 30, 2019	$(9.23)	
Increase attributable to pro forma adjustments		
Pro forma net tangible book value per share as of September 30, 2019		
Increase in pro forma net tangible book value per share attributable to new investors in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution in pro forma as adjusted net tangible book value per share to new investors in this offering		$

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) our

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

pro forma as adjusted net tangible book value by $ million, or $ per share and the dilution in pro forma as adjusted net tangible book value per share to new investors in this offering by $ per share, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million in the number of shares offered by us in this offering would increase our pro forma as adjusted net tangible book value by approximately $ million, or approximately $ per share, and would decrease dilution per share to new investors in this offering by approximately $ per share, and each decrease of 1.0 million in the number of shares offered by us in this offering would decrease our pro forma as adjusted net tangible book value by approximately $ million, or approximately $ per share, and would increase dilution per share to new investors in this offering by approximately $ per share, in each case assuming the initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option in full to purchase additional shares, the pro forma as adjusted net tangible book value per share after this offering would be $ per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $ per share and the dilution to new investors in this offering would be $ per share.

The following table shows, as of September 30, 2019, on a pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration and the average price per share (i) paid to us by existing stockholders and (ii) to be paid by new investors acquiring our common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the over page of this prospectus, before deducting underwriting discounts and commission and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					$
Total		100.0%	$	100.0%	

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) total consideration paid by new investors by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares offered by us in this offering would increase (decrease) total consideration paid by new investors by approximately $ million, assuming the initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares. If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding upon the completion of this offering.

The number of shares of our common stock to be outstanding after this offering is based on 54,522,960 shares of our common stock outstanding as of September 30, 2019, including

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

1,777,301 shares of unvested common stock subject to repurchase, assuming the conversion of all our outstanding shares of convertible preferred stock, including 16,251,628 shares of Series C convertible preferred stock issued in October 2019, into an aggregate of 48,787,895 shares of our common stock immediately prior to completion of this offering, and excludes:

- 3,147,770 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2019 under our 2017 Equity Incentive Plan, with an average exercise price of $0.80 per share;
- shares of common stock issuable upon the exercise of options outstanding that were granted after September 30, 2019 under our 2017 Equity Incentive Plan, with an average exercise price of $ per share;
- 2,191,014 shares of common stock reserved for future issuance under our 2017 Equity Incentive Plan as of September 30, 2019, which will cease to be available for issuance at the time that our 2020 Equity Incentive Plan becomes effective;
- 2,823,831 additional shares of common stock reserved for future issuance under our 2017 Equity Incentive Plan after September 30, 2019 in connection with the sale of Series C convertible preferred stock in October 2019, which will cease to be available for issuance at the time that our 2020 Equity Incentive Plan becomes effective;
- shares of common stock that will become available for future issuance under our 2020 Equity Incentive Plan upon the effectiveness of the registration statement of which this prospectus forms a part; and shares of common stock that will become available for future issuance under our 2020 Employee Stock Purchase Plan upon the effectiveness of the registration statement of which this prospectus forms a part. Upon completion of this offering, any remaining shares available for issuance under our 2017 Equity Incentive Plan will be added to the shares reserved under our 2020 Equity Incentive Plan and we will cease granting awards under our 2017 Equity Incentive Plan. Our 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan also provide for automatic annual increases in the number of shares reserved under the plans each year, as more fully described in “Executive Compensation—Equity Compensation Plans and Other Benefit Plans.”

In addition, to the extent that any outstanding options are exercised, investors in this offering will experience further dilution.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

SELECTED FINANCIAL DATA

The following tables set forth our selected statements of operations and balance sheet data. The selected statements of operations data for the years ended December 31, 2017 and 2018, and the selected balance sheet data as of December 31, 2017 and 2018, are derived from our audited financial statements and the related notes thereto included elsewhere in this prospectus, which financial statements have been audited by our independent registered public accounting firm. We derived our summary statements of operations data for the nine months ended September 30, 2018 and 2019 and our summary balance sheet data as of September 30, 2019 from our unaudited interim condensed financial statements and the related notes thereto included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles on the same basis as our audited annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal, recurring adjustments, that are necessary for the fair statement of our financial position as of September 30, 2019 and our results of operations for the nine months ended September 30, 2018 and 2019. The following selected financial data below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Nine Months Ended September 30,	
	2017	2018	2018	2019
			(unaudited)	
	(in thousands, except share and per share data)			
Statements of operations data:				
Operating expenses:				
Research and development	$ 3,411	$ 17,940	$ 12,593	$ 25,765
General and administrative	695	1,795	1,189	4,373
Total operating expenses	4,106	19,735	13,782	30,138
Loss from operations	(4,106)	(19,735)	(13,782)	(30,138)
Other income (expense), net	(872)	480	128	710
Net loss	$ (4,978)	$ (19,255)	$ (13,654)	$ (29,428)
Net loss per share, basic and diluted(1)	$ (3.58)	$ (7.76)	$ (5.92)	$ (8.30)
Weighted-average shares used in computing net loss per share, basic and diluted(1)	1,391,097	2,480,246	2,305,932	3,547,292
Pro forma net loss per share, basic and diluted (unaudited)(1)		$		$
Weighted-average shares used in computing pro forma net loss per share, basic and diluted (unaudited)(1)				

(1) See Notes 2, 11 and 12 to our audited financial statements and Notes 2, 10 and 11 to our unaudited interim condensed financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per share and basic and diluted pro forma net loss per share, and the weighted-average number of shares used in the computation of these per share amounts.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

	December 31,		September 30,
	2017	2018	2019
			(unaudited)
		(in thousands)	
Balance sheet data:			
Cash, cash equivalents, and marketable securities	$ 3,418	$ 50,940	$ 25,177
Working capital(1)	3,127	48,425	19,172
Total assets	3,819	51,098	28,303
Convertible preferred stock	7,154	72,252	72,252
Accumulated deficit	(5,021)	(24,276)	(53,704)
Total stockholders' deficit	(4,993)	(23,987)	(52,950)

(1) We define working capital as current assets less current liabilities. See our financial statements and related notes appearing at the end of this prospectus for further details regarding our current assets and current liabilities.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our "Selected Financial Data" and our audited financial statements and related notes and unaudited interim condensed financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans, objectives, expectations, projections and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors identified below and those set forth in the "Risk Factors" section of this prospectus, our actual results and the timing of selected events could differ materially from the forward-looking statements contained in the following discussion and analysis. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. Our current portfolio is comprised of topical treatments with significant potential to address immune-mediated dermatological diseases and conditions, or immuno-dermatology. Our strategy is to identify and develop treatments against validated biological targets in dermatology that deliver a differentiated clinical profile that addresses major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product candidate, ARQ-151, is a topical cream formulation of roflumilast, a highly potent and selective phosphodiesterase type 4, or PDE4, inhibitor, which we are developing for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. In July 2018, we executed a licensing agreement with AstraZeneca AB, or AstraZeneca, for exclusive worldwide rights to all topical dermatological uses of roflumilast. We have successfully completed a Phase 2b study of ARQ-151 in plaque psoriasis, and, in August 2019, paid AstraZeneca the first milestone payment of $2.0 million that was earned upon the achievement of positive Phase 2 data for any AZ-Licensed Product (as defined in "—License Agreements—AstraZeneca License Agreement"). We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, and expect to report topline data in the first half of 2021. After holding a positive End-of-Phase 2 Meeting with the FDA in October 2019, we will initiate Phase 3 studies in plaque psoriasis in the first half of 2020 and expect to report topline data in the first half of 2021. We also have completed enrollment of a Phase 2a study of ARQ-151 in atopic dermatitis, and expect to report topline results from this study by the end of 2019. If successful, we plan to initiate a Phase 2b study in atopic dermatitis in the second half of 2020 with topline results in the second half of 2021. In addition, we are developing ARQ-154, a topical foam formulation of ARQ-151, and will advance this product candidate into Phase 2b studies in both scalp psoriasis and seborrheic dermatitis in Q4 2019/Q1 2020, and expect to report topline data in Q4 2020/Q1 2021 with respect to scalp psoriasis and the second half of 2020 with respect to seborrheic dermatitis. Beyond this, in 2020, we also plan to initiate clinical studies of ARQ-252, a potent and highly selective topical janus kinase type 1, or JAK1, inhibitor for the treatment of hand eczema and vitiligo. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. In January 2018, we executed an exclusive option and license agreement with Jiangsu Hengrui Medicine Co., Ltd. of China, or Hengrui, to the active pharmaceutical ingredient in ARQ-252 and ARQ-255 for all topical formulations for dermatological uses in the United States, Europe and Japan.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Since our inception in 2016, we have invested a significant portion of our efforts and financial resources in research and development activities. We have not generated any revenue from product sales and, to date, have funded our operations primarily with $68.3 million in net cash proceeds from private placements of our convertible preferred stock as of September 30, 2019. In October 2019, we received an additional $94.5 million in gross cash proceeds by selling an aggregate of 16,251,628 shares of our Series C convertible preferred stock. We have incurred net losses in each year since inception, including net losses of $5.0 million and $19.3 million for the years ended December 31, 2017 and 2018, respectively, and $13.7 million and $29.4 million for the nine months ended September 30, 2018 and 2019, respectively. As of September 30, 2019, we had an accumulated deficit of $53.7 million and cash, cash equivalents and marketable securities of $25.2 million.

We expect to continue to incur losses for the foreseeable future and expect to incur increased expenses as we advance our product candidates through clinical trials and regulatory submissions. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval or clearance from the FDA or other foreign regulatory authorities for our product candidates. If we obtain regulatory approval or clearance for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue preclinical studies and clinical trials for, and research and development of, our product candidates and maintain, expand and protect our intellectual property portfolio and begin operating as a public company. As a result, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through equity or debt financings or other sources, such as future potential collaboration agreements. Our failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations and financial condition. See “—Liquidity, Capital Resources and Requirements” below and Note 1 to the financial statements and interim condensed financial statements for additional information. Based on our current planned operations, we expect that the net proceeds from this offering, together with our existing cash, cash equivalent, and marketable securities, will be sufficient to fund our operations through at least the next 12 months.

We rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our product candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, many of whom are single-source suppliers, for our preclinical and clinical trial materials, as well as the commercial supply of our products. In addition, we do not yet have a sales organization or commercial infrastructure. Accordingly, we will incur significant expenses to develop a sales organization or commercial infrastructure in advance of generating any product sales.

License Agreements

AstraZeneca License Agreement

In July 2018, we entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca, granting us a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, commercialize and otherwise exploit products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, the AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. Under this agreement, we have sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at our expense, and we shall use commercially reasonable efforts

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

to develop, obtain and maintain regulatory approvals for, and commercialize the AZ-Licensed Products in the Dermatology Field in each of the United States, Italy, Spain, Germany, the United Kingdom, France, China, and Japan.

We paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 969,117 shares of our Series B Preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. In addition, we have agreed to make cash payments to AstraZeneca of up to an aggregate of $14.5 million upon the achievement of specified clinical development and regulatory approval milestones with respect to the AZ-Licensed Products and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. The first milestone cash payment of $2.0 million was earned upon the achievement of positive Phase 2 data for any AZ-Licensed Product, and we paid this in August 2019 upon the completion of a Phase 2b study of ARQ-151 in plaque psoriasis. For more information, please see "Business—Exclusive License and Option Agreements."

Hengrui Exclusive Option and License Agreement

In January 2018, we entered into an exclusive option and license agreement, or Hengrui License Agreement, with Hengrui, whereby Hengrui granted us an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, and the European Union (including for clarity the United Kingdom). The initial option period under the Hengrui License Agreement extended to June 2019, and was subsequently amended to extend until January 2020. We made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui License Agreement. If we exercise our exclusive option, we will pay Hengrui an additional $1.5 million option exercise cash payment. In addition, if exercised, we have agreed to make cash payments of up to an aggregate of $20.5 million upon our achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $200.0 million in sales-based milestones based on achieving certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products we commercialize under the Hengrui License Agreement, we will pay tiered royalties to Hengrui on net sales of each licensed product by us, or our affiliates, or our sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the later of (1) expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, we are obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income we receive from sublicensees of our rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance. For more information, please see "Business—Exclusive License and Option Agreements."

Hawkeye Collaboration Agreement

In June 2019, we entered into a collaboration agreement, or the Hawkeye Agreement, with Hawkeye Therapeutics, Inc., or Hawkeye, a related party with common ownership, to collaborate on

the research and development of one or more new applications of roflumilast. The Hawkeye Agreement grants Hawkeye an exclusive license to certain intellectual property developed under the agreement as it relates to the applications. Under the terms of the Hawkeye Agreement, we are required to perform certain research and development activities that are fully funded by Hawkeye.

Contemporaneously with the execution of the Hawkeye Agreement, we entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye's common stock at $0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye. The shares are subject to a right to repurchase by Hawkeye which vests monthly over the six-month term of the Hawkeye Agreement. See Note 6 to the interim condensed financial statements for additional information.

Components of Our Results of Operations

Revenue

We have not generated any revenue from the sale of our products, and we do not expect to generate any revenue unless and until we obtain regulatory clearance or approval of, and commercialize, our product candidates.

Operating Expenses

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. Research and development costs are expensed as incurred. These costs include direct program expenses, which are payments made to third parties that specifically relate to our research and development, such as payments to clinical research organizations, clinical investigators, manufacturing of clinical material, preclinical testing and consultants. In addition, employee costs, including salaries, payroll taxes, benefits, stock-based compensation and travel, for employees contributing to research and development activities are classified as research and development costs. We allocate direct external costs to our product candidates; internal costs are not allocated to specific product candidates.

We expect to continue to incur substantial research and development expenses in the future as we develop our product candidates. In particular, we expect to incur substantial research and development expenses for the Phase 3 trials of ARQ-151 for plaque psoriasis, including in the intertriginous regions, the preclinical studies and clinical trials for the continued development of ARQ-151 for atopic dermatitis, ARQ-154 for seborrheic dermatitis and scalp psoriasis, ARQ-252 for hand eczema and vitiligo, and ARQ-255 for alopecia areata.

We have entered, and may continue to enter, into license agreements to access and utilize certain molecules for the treatment of dermatological diseases and disorders. We evaluate if the license agreement is an acquisition of an asset or a business. To date, none of our license agreements have been considered to be an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval, are immediately recognized as research and development expense when due, provided there is no alternative future use of the rights in other research and development projects.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of ARQ-151, ARQ-154, ARQ-252 and ARQ-255 or any future product candidates. This is due to the

numerous risks and uncertainties associated with the development of product candidates. See “Risk Factors” for a discussion of the risks and uncertainties associated with our research and development projects.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, stock-based compensation and travel. Other general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, and professional services fees for auditing, tax and general legal services. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and prepare for potential commercialization of our product candidates, increase our headcount and support our operations as a public company, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, directors and officers liability insurance premiums and investor relations activities.

Other Income (Expense), Net

Other income (expense), net primarily consists of changes in the fair value of our convertible preferred stock liability and interest income earned on our marketable securities.

Results of Operations

Comparison of the Nine Months Ended September 30, 2018 and 2019

The following table sets forth our results of operations for the periods indicated:

	Nine Months Ended September 30,		
	2018	2019	Change
		(unaudited) (in thousands)	
Operating expenses:			
Research and development	$ 12,593	$ 25,765	$ 13,172
General and administrative	1,189	4,373	3,184
Total operating expenses	13,782	30,138	16,356
Loss from operations	(13,782)	(30,138)	(16,356)
Other income, net	128	710	582
Net loss	$(13,654)	$(29,428)	$(15,774)

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PURSUANT TO 17 C.F.R. SECTION 200.83**

Research and Development Expenses

	Nine Months Ended September 30,		
	2018	2019	Change
		(unaudited) (in thousands)	
Direct Costs:			
Preclinical and clinical	$ 5,336	$16,737	$11,401
Manufacturing	1,064	2,574	1,510
Product milestones	4,400	2,000	(2,400)
Indirect Costs:			
Compensation and personnel-related	1,730	4,142	2,412
Other	63	312	249
Total research and development expense	$12,593	$25,765	$13,172

Research and development expenses were $25.8 million for the nine months ended September 30, 2019, compared to $12.6 million for the nine months ended September 30, 2018. The increase of $13.2 million was primarily due to an increase in clinical trial costs of $11.4 million, an increase in compensation and personnel-related expenses of $2.4 million and an increase in manufacturing costs of $1.5 million, partially offset by a decrease in product milestone payments of $2.4 million. The increases in clinical trial costs and manufacturing costs relate to the initiation of the Phase 2b and open label extension studies in ARQ-151 for plaque psoriasis in the second half of 2018 and the initiation of Phase 2 study in ARQ-151 in atopic dermatitis in early 2019. The increase in compensation and personnel-related expenses was primarily due to an increase in headcount, which includes stock compensation. Product milestones consisted of a $4.0 million upfront payment to AstraZeneca in the nine months ended September 30, 2018, comprised of $1.0 million paid in cash and the issuance of $3.0 million in shares of our Series B Convertible preferred stock, a $0.4 million cash payment made to Hengrui for the option to obtain a license in the nine months ended September 30, 2018, as well as a $2.0 million cash milestone payment made to AstraZeneca in the nine months ended September 30, 2019.

General and Administrative Expenses

General and administrative expenses were $4.4 million for the nine months ended September 30, 2019, compared to $1.2 million for the nine months ended September 30, 2018. The increase of $3.2 million was primarily due to an increase in professional services of $1.8 million, which includes legal, tax, audit, recruiting, market research studies and various other administrative functions, as well as an increase of $1.2 million in compensation and personnel-related expenses due to an increase in headcount, which includes stock compensation.

Other Income, Net

Other income, net was $0.7 million for the nine months ended September 30, 2019, compared to $0.1 million for the nine months ended September 30, 2018. The increase of $0.6 million was primarily due to interest earned on our marketable securities from the funds received from the issuance of our Series B convertible preferred stock in the nine months ended September 30, 2018.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Comparison of the Years Ended December 31, 2017 and 2018

The following table sets forth our results of operations for the periods indicated:

	Year Ended December 31,		
	2017	2018	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 3,411	$ 17,940	$ 14,529
General and administrative	695	1,795	1,100
Total operating expenses	4,106	19,735	15,629
Loss from operations	(4,106)	(19,735)	(15,629)
Other income (expense), net	(872)	480	1,352
Net loss	$(4,978)	$(19,255)	$(14,277)

Research and Development Expenses

	Year Ended December 31,		
	2017	2018 (unaudited)	Change
		(in thousands)	
Direct Costs:			
Preclinical and clinical	$2,166	$ 8,448	$ 6,282
Manufacturing	271	2,493	2,222
Product milestones	—	4,400	4,400
Indirect Costs:			
Compensation and personnel-related	459	1,566	1,107
Other	515	1,033	518
Total research and development expense	$3,411	$ 17,940	$14,529

Research and development expenses were $17.9 million for the year ended December 31, 2018, compared to $3.4 million for the year ended December 31, 2017. The increase of $14.5 million was due to increases in clinical trial costs of $6.3 million, product milestones of $4.4 million, manufacturing costs of $2.2 million, compensation and personnel-related expenses of $1.1 million, and regulatory and clinical consulting costs of $0.5 million. The increase in clinical trial and manufacturing costs were related to our Phase 2a and Phase 2b clinical trials of ARQ-151 for the treatment of plaque psoriasis, which were initiated in 2018. Product milestones consisted of a $4.0 million upfront payment to AstraZeneca, comprised of $1.0 million paid in cash and the issuance of $3.0 million in shares of our Series B convertible preferred stock during 2018, as well as a $0.4 million cash payment made to Hengrui for the option to obtain a license. The increase in compensation and personnel-related expenses was due to an increase in headcount, which includes stock compensation.

General and Administrative Expenses

General and administrative expenses were $1.8 million for the year ended December 31, 2018, compared to $0.7 million for the year ended December 31, 2017. The increase of $1.1 million was primarily due to an increase of $0.6 million in compensation and personnel-related expenses due to an increase in headcount, which includes stock compensation. The increase was also driven by increases in professional services of $0.5 million for legal, recruiting, market research studies and other administrative services.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Other Income (Expense), Net

Other income (expense), net was income of $0.5 million for the year ended December 31, 2018, compared to expense of $0.9 million for the year ended December 31, 2017. The change of $1.4 million was due to an increase in interest income of $0.4 million from interest earned on the funds received from the issuance of convertible preferred stock in 2018, and a decrease in expense of $0.8 million primarily from the fair value remeasurement of the Series A convertible preferred stock liability and $0.2 million from the fair value remeasurement of the derivative liability related to our promissory notes payable that converted into Series A convertible preferred stock in 2017.

Liquidity, Capital Resources and Requirements

Sources of Liquidity

We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. As of September 30, 2019, we had cash, cash equivalents and marketable securities of $25.2 million and an accumulated deficit of $53.7 million. In October 2019, we received an additional $94.5 million in gross cash proceeds by selling an aggregate of 16,251,628 shares of our Series C convertible preferred stock. We anticipate that operating losses and net cash used in operating activities will increase over the next several years as we further develop ARQ-151, ARQ-154, ARQ-252 and ARQ-255, move into later and more costly stages of product development, develop new product candidates, hire personnel and prepare for regulatory submissions and the commercialization of our product candidates.

We have historically financed our operations primarily through private placements of preferred stock and will continue to be dependent upon equity, debt financing or collaborations or other forms of capital at least until we are able to generate positive cash flows from our operations.

Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Year Ended December 31,		Nine Months Ended September 30,	
	2017	2018	2018	2019
			(unaudited)	
	(in thousands)			
Cash used in operating activities	$(3,775)	$(14,085)	$ (8,247)	$(26,039)
Cash used in investing activities	—	(11,532)	—	9,674
Cash provided by financing activities	7,119	61,593	61,593	148
Net increase (decrease) in cash and cash equivalents	$ 3,344	$ 35,976	$53,346	$(16,217)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2019, net cash used in operating activities was $26.0 million which consisted of a net loss of $29.4 million, adjusted by net non-cash charges of $0.1 million and a change in net operating assets and liabilities of $3.2 million. The change in net operating assets and liabilities was due to an increase of $5.7 million in accounts payable and accrued liabilities due to our overall growth, increased research and development spending and timing of payments, partially offset by an increase of $2.3 million in prepaid expenses and other current assets for advances made for clinical trial costs.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

During the nine months ended September 30, 2018, net cash used in operating activities was $8.2 million which consisted of a net loss of $13.7 million, adjusted by net non-cash charges of $3.0 million and a change in net operating assets and liabilities of $2.4 million. The net non-cash changes were primarily related to the issuance of convertible preferred stock in connection with the AstraZeneca License Agreement, which was expensed to research and development. The change in our net operating assets and liabilities was primarily due to an increase of $2.4 million in accounts payable and accrued liabilities due to our overall growth, increased research and development spending and timing of payments.

During the year ended December 31, 2018, net cash used in operating activities was $14.1 million and consisted primarily of a net loss of $19.3 million adjusted by non-cash charges of $3.1 million and a change of $2.1 million in our net operating assets and liabilities. The non-cash charges were primarily related to the issuance of convertible preferred stock in connection with the AstraZeneca License Agreement, which was expensed to research and development. The change in our net operating assets and liabilities was primarily due to a net increase of $1.9 million in accounts payable and accrued liabilities due to our overall growth, increased research and development spending and timing of payments.

During the year ended December 31, 2017, net cash used in operating activities was $3.8 million and consisted primarily of a net loss of $5.0 million, adjusted by non-cash charges of $0.9 million and a change of $0.3 million in our net operating assets and liabilities. The non-cash charges consisted of a loss from fair value remeasurement of our convertible preferred stock liability of $0.7 million and a loss from fair value measurement of the derivative liability of $0.2 million due to the conversion of our promissory notes payable into Series A convertible preferred stock. The change in our net operating assets and liabilities was primarily due to a net increase of $0.7 million in accounts payable and accrued liabilities due to our overall growth, increased research and development spending and timing of payments. These changes were partially offset by an increase of $0.4 million in prepaid expenses and other current assets for advances made for clinical trial costs.

Net Cash Used in Investing Activities

During the nine months ended September 30, 2019, net cash provided by investing activities was $9.7 million and was comprised of proceeds from the maturities of marketable securities of $32.8 million, partially offset by marketable securities of $22.9 million and property and equipment of $0.2 million.

During the year ended December 31, 2018, net cash used in investing activities was $11.5 million, which represented the purchase of marketable securities.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2019, net cash provided by financing activities was $0.1 million from the proceeds received from the exercise of stock options of $0.3 million, partially offset by payments of financing costs associated with our Series C convertible preferred stock issuance of $0.1 million.

During the nine months ended September 30, 2018, net cash provided by financing activities was $61.6 million, which was comprised of $61.2 million from proceeds received from the second closing of our Series A and our Series B convertible preferred stock financing as well as $0.4 million from proceeds received from the exercise of stock options.

During the year ended December 31, 2018, net cash provided by financing activities was $61.6 million, consisting of $61.2 million in proceeds from the issuance of our Series A and Series B convertible preferred stock and $0.4 million from proceeds received from the exercise of stock options.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

During the year ended December 31, 2017, net cash provided by financing activities was $7.1 million, primarily consisting of proceeds from the issuance of our Series A convertible preferred stock.

Funding Requirements

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $53.7 million as of September 30, 2019. We had cash, cash equivalents and marketable securities of $25.2 million as of September 30, 2019. In October 2019, we received an additional $94.5 million in gross cash proceeds by selling an aggregate of 16,251,628 shares of our Series C convertible preferred stock. Based on our current planned operations, we expect that our current cash, cash equivalents and marketable securities, including the cash proceeds received in connection with the issuance of our Series C convertible preferred stock, will be sufficient to fund our operations for at least 12 months after the date our most recent financial statements were issued. As noted in our 2018 audited financial statements, there were conditions that raised substantial doubt about our ability to continue as a going concern for a period of one year from the date of the issuance of our 2018 financial statements. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

We will need to raise substantial additional capital to fund our operations through the sale of our equity securities, incurring debt, entering into licensing or collaboration agreements with partners, grants or other sources of financing. There can be no assurance that sufficient funds will be available to us at all or on attractive terms when needed from these sources. If we are unable to obtain additional funding from these or other sources when needed it may be necessary to significantly reduce our current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our planned Phase 3 studies of ARQ-151 in plaque psoriasis, our planned Phase 2b studies of ARQ-154 in scalp psoriasis and seborrheic dermatitis, our planned Phase 2b study of ARQ-252 in hand eczema, our planned Phase 2a study of ARQ-252 in vitiligo and our formulation and preclinical efforts for ARQ-255 for alopecia areata.
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead product candidate or our other product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our lead product candidates or any future product candidates and any products we successfully commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities if our lead product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs;

- the cost of building a sales force in anticipation of product commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the costs related to milestone payments to AstraZeneca or Hengrui, upon the achievement of predetermined milestones;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, and the outcome of this and any other future patent litigation we may be involved in; and
- the timing, receipt and amount of sales of any future approved products, if any.

Contractual Obligations and Contingent Liabilities

We had no significant contractual obligations as of December 31, 2018. The following summarizes our significant contractual obligations as of September 30, 2019:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating leases	$371	$ 191	$180	$ —	$ —
Total obligations	$371	$ 191	$180	$ —	$ —

We entered into a lease agreement in January 2019 for our headquarters in Westlake Village, California. The term of the lease commenced in March 2019 and terminates in July 2021. The total estimated lease payments for this facility over the term of the lease is approximately $0.5 million.

We are party to license agreements pursuant to which we have in-licensed various intellectual property rights. The license agreements obligate us to make certain milestone payments related to achievement of specified events, as well as royalties in the low-single digits based on sales of licensed products. None of these events had occurred as of September 30, 2019, and no royalties were due from the sales of licensed products. The table above does not include any milestone or royalty payments to the counterparties to these agreements as the amounts, timing and likelihood of such payments are not known. See Note 6 to our audited financial statements and Note 5 to our unaudited interim condensed financial statements for additional information.

We enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have

not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our certificate of incorporation and bylaws, we have indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

Preclinical and Clinical Accruals and Costs

We record accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical studies, clinical trials and contract manufacturing activities. These costs are a significant component of our research and development expenses. Research and development costs are expensed as incurred unless there is an alternative future use in other research and development projects. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with third-party service providers under the service agreements. As it relates to clinical trials, the financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized. Our objective is to reflect the appropriate expense in our financial statements by matching those expenses with the period in which the services and efforts are expended. We account for these

expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial utilizing financial models taking into consideration discussions with applicable personnel and outside service providers. During the course of a clinical trial, we adjust the rate of clinical expense recognition if actual results differ from our estimates. We make significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust our accrued liabilities. We have not experienced any material differences between accrued costs as of December 31, 2017 and 2018 and September 30, 2019 and actual costs incurred.

Stock-Based Compensation

We account for share-based payments at fair value. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for such awards is the date of grant and the expense is recognized on a straight-line basis, over the expected vesting period. For share-based awards that vest subject to a performance condition, we recognize compensation cost for awards if and when we conclude that it is probable that the awards with a performance condition will be achieved on an accelerated attribution method. We account for forfeitures as they occur.

We calculate the fair value measurement of stock options using the Black-Scholes option pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgement.

Fair value of common stock—see the subsection titled “Common Stock Valuations” below.

Expected Term—The expected term represents the period that we expect our stock-based awards to be outstanding. We used the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term.

Expected Volatility—Since we are privately held and do not have any trading history for our common stock, the expected volatility was estimated based on the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Dividend Yield—We have never paid dividends on common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 9 to our audited financial statements and to our unaudited interim condensed financial statements included elsewhere in this prospectus for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

We recorded stock-based compensation expense of $27,000 and $151,000 for the years ended December 31, 2017 and 2018, respectively and $95,000 and $369,000 for the nine months ended September 30, 2018 and 2019, respectively. As of September 30, 2019, there was $1.9 million of

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PURSUANT TO 17 C.F.R. SECTION 200.83**

unrecognized compensation expense related to unvested options, which are expected to be recognized over a weighted-average period of approximately 3.5 years. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

Based upon the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, the aggregate intrinsic value of options outstanding as of September 30, 2019 was $ million, of which $ million related to vested options and $ million related to unvested options.

Common Stock Valuation

There are significant assumptions and estimates required in determining the fair value of our common stock. Due to the absence of an active market for our common stock, the fair value of our common stock was determined in good faith by our board of directors, with the assistance and upon the recommendation of management and valuations of our common stock prepared by an unrelated third-party valuation firm, based on a number of objective and subjective factors consistent with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, referred to as the AICPA Practice Aid, including:

- contemporaneous valuations of our shares of common stock;
- the prices of each of our series of preferred stock sold by us to outside investors in arm's length transactions, and the rights, preferences and privileges of each of these series of preferred stock relative to our common stock;
- our results of operations, financial position and the status of our research and development efforts;
- the composition of our management team and board of directors;
- the material risks related to our business;
- the market performance of publicly traded companies in the life sciences and biotechnology sectors;
- the likelihood of achieving a liquidity event for the holders of our shares of common stock, such as a sale of the company or an initial public offering, given prevailing market conditions;
- the lack of marketability of our common stock; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

Although it is reasonable to expect that the completion of our initial public offering will increase the value of our common stock as a result of increased liquidity and marketability and the elimination of the liquidation preferences of our convertible preferred stock, the amount of additional value cannot be measured with precision or certainty. If we had made different assumptions than those described below, the fair value of the underlying common stock and amount of our stock-based compensation expense, net loss and net loss per share amounts would have differed. Following the closing of our initial public offering, the fair value per share of our common stock for purposes of determining stock-based compensation will be the closing price of our common stock as reported on the applicable grant date.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

The following table summarizes the grant dates, number of underlying shares and related fair value of stock options granted to employees under the plan:

Date of Grant	Number of shares underlying option grants	Exercise price per share ($)	Per share estimated fair value of common stock ($)
March 9, 2018	390,431	0.18	0.56
June 13, 2018	1,109,149	0.29	0.59
November 21, 2018	175,000	0.84	0.84
March 5, 2019	373,750	0.84	0.84
March 13, 2019	1,767,200	0.84	0.84
May 14, 2019	550,000	0.84	0.84
June 11, 2019	240,000	0.84	0.84
October 18, 2019	340,000	3.26	3.26
October 28, 2019	580,000	3.26	3.26

Historically, for all periods prior to this offering, fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. Our board of directors considered, among other things, valuations of our common stock which were prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Prior to October 2019, we used the Backsolve Method to determine the fair value of our common stock. The Backsolve Method utilizes a recent equity financing, in our case, our Series A and Series B convertible preferred stock financings, to back into the implied equity value. The equity value was then allocated to the equity classes using an option pricing method and then reducing the implied common stock value by a discount for lack of marketability. The resulting fair value of our common stock as of our April 2017, March 2018 and August 2018 valuation dates was $0.18, $0.29, and $0.84 per share, respectively. In October 2019, we utilized a hybrid approach to determine the fair value of our common stock, based on the Backsolve Method taking into consideration the implied equity value based on the recent Series C financing. Under the hybrid method, we probability weighted the value of our common stock, adjusted for discount for lack of marketability, under three distinct scenarios: (i) an initial public offering, (ii) a delayed initial public offering, and (iii) utilizing the option pricing method assuming a stay private with the possibility of exiting later. The resulting fair value of our common stock, as of October 2019, was determined to be $3.26.

In 2019, we reassessed the determination of the fair value of the common shares underlying the grants made prior to August 2018 in connection with a valuation of the convertible preferred stock liability. This analysis revised our implied equity value, which was then allocated to each equity class using an option pricing method and the implied value of common stock was then reduced by a discount for lack of marketability. As a result of this reassessment, we determined that fair value of common stock increased to $0.23, $0.56 and $0.59 per share as of April 2017, December 2017 and March 2018, respectively. The increase to both recognized and unrecognized share-based compensation expense due to these higher share prices was approximately $86,000 and $0.4 million, respectively, as of December 31, 2018.

Income Taxes

As of December 31, 2018, we had deferred tax assets of $5.3 million. The deferred tax assets have been offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of net operating loss, or NOL, tax

carryforwards. As of December 31, 2018, we had federal and state NOL carryforwards of $17.2 million and $18.1 million, respectively, available to potentially offset future taxable income. As of December 31, 2018, we also had federal and California research and development tax credit carryforwards of approximately $0.8 million and $0.3 million, respectively, available to potentially offset future federal income taxes. The federal research and development tax carryforwards, if not utilized, will expire beginning in 2037. The California research and development tax credit carryforwards are available indefinitely. Federal and California tax law impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership, as defined by Internal Revenue Code Section 382 and 383. We have not completed a formal study to determine any limitations on our tax attributes due to changes in ownership and may have limitations on the utilization of net operating loss carryforwards, credit carryforwards, or other tax attributes due to ownership changes.

Recent Accounting Pronouncements

We adopted Accounting Standards Update, or ASU, No. 2016-02, *Leases (Topic 842)*, on January 1, 2019. As of December 31, 2018, we had not entered into any leases within the scope of the standard and there was no impact to our unaudited interim condensed financial statements upon adoption.

See Note 2 to our audited financial statements and unaudited interim condensed financial statements included elsewhere in this prospectus for more information.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of September 30, 2019, we had cash and cash equivalents of $23.2 million and marketable securities of $2.0 million, which consist of bank deposits, money market funds, commercial paper and government securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of September 30, 2019.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we are (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We early adopted ASU 2016-01, *Financial Instruments—Overall (Topic 825)—Recognition and Measurement of Financial Assets and Financial Liabilities*, ASU 2016-09, *Compensation—Stock Compensation (Topic 718)—Improvements to Employee Share Based Payment Accounting*, ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, and ASU No. 2016-02, *Leases* as the JOBS Act does not preclude an emerging growth company from early adopting a new or revised accounting standard earlier than the time such standard applies to

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

private companies. We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. Our current portfolio is comprised of topical treatments with significant potential to address immune-mediated dermatological diseases and conditions, or immuno-dermatology. Our strategy is to identify and develop treatments against validated biological targets in dermatology that deliver a differentiated clinical profile that addresses major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product candidate, ARQ-151, is a topical cream formulation of roflumilast, a highly potent and selective phosphodiesterase type 4, or PDE4, inhibitor, which we are developing for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. PDE4 is an established biological target in dermatology, with multiple PDE4 inhibitors approved by the U.S. Food and Drug Administration, or FDA. We have successfully completed a Phase 2b study of ARQ-151 in plaque psoriasis, and have treated more than 425 plaque psoriasis patients, demonstrating potential symptomatic improvement and favorable tolerability of ARQ-151 in this population. We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, and expect to report topline data in the first half of 2021. After holding a positive End-of-Phase 2 Meeting with the FDA in October 2019, we will initiate Phase 3 studies in plaque psoriasis in the first half of 2020 and expect to report topline data in the first half of 2021. We also have completed enrollment of a Phase 2a study of ARQ-151 in atopic dermatitis, and expect to report topline results from this study by the end of 2019. If successful, we plan to initiate a Phase 2b study in atopic dermatitis in the second half of 2020 with topline results in the second half of 2021. In addition, we are developing ARQ-154, a topical foam formulation of ARQ-151, and will advance this product candidate into Phase 2b studies in both scalp psoriasis and seborrheic dermatitis in Q4 2019/Q1 2020, and expect to report topline data in Q4 2020/Q1 2021 with respect to scalp psoriasis and the second half of 2020 with respect to seborrheic dermatitis. Beyond this, in 2020 we also plan to initiate clinical studies of ARQ-252, a potent and highly selective topical janus kinase type 1, or JAK1, inhibitor for the treatment of hand eczema and vitiligo. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

Dermatological diseases such as psoriasis, atopic dermatitis, seborrheic dermatitis, hand eczema, alopecia areata, and vitiligo affect hundreds of millions of people worldwide each year, impacting their quality of life, and physical, functional and emotional well-being. There are many approved treatments for these conditions, but a large opportunity remains due to issues with existing treatments. Topical treatments are used for nearly all patients, but are limited by one or more of the following: modest response rates, side effects, patient adherence, application site restrictions, and limits on duration of therapy. Topical corticosteroids, or TCS, are commonly used as the first-line therapy for the treatment of inflammatory skin conditions such as psoriasis and atopic dermatitis. While many patients see improvements, long term TCS treatment carries the risk of a variety of significant side effects. As a result, TCS are typically used intermittently, which can lead to disease flares. In psoriasis, vitamin D analogues have demonstrated lower response rates than TCS and are frequently irritating. In atopic dermatitis, topical calcineurin inhibitors, or TCIs, and Eucrisa have lower response rates than TCS and are associated with application site burning. TCIs also have a boxed warning for cancer risk.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

Biologic and systemic therapies are also available, but are indicated for a small percentage of the affected population. Biologics for psoriasis and atopic dermatitis have shown impressive response rates but are only indicated for patients with moderate-to-severe forms of disease, are expensive, and often face reimbursement and access restrictions. Use of oral systemic therapies such as methotrexate and Otezla are also limited to more severe psoriasis patients and have significant side effect risks. Additionally, many patients on biologic and systemic therapies still require adjunctive topical therapy.

Given the limitations associated with TCS, other topical therapies, biologics, and systemic therapies, we believe patients with inflammatory skin conditions are dissatisfied with their current treatment options. We believe that there is a significant opportunity to leverage developments in other fields of medicine, particularly inflammation and immunology, to address the significant need for effective chronic treatments in immuno-dermatology. Our initial focus is to address patients' significant need for innovative topical treatments that directly target molecular mediators of disease, have the potential to show significant symptomatic improvement, maintain a low risk of toxicity or side effects, and are suitable for chronic use on all areas of the body.

We are developing ARQ-151 for the treatment of plaque psoriasis and atopic dermatitis. High-potency steroids are the current standard of care for plaque psoriasis, and low- to mid-potency steroids are the current standard of care for atopic dermatitis, but steroids are associated with suppression of the hypothalamic-pituitary-adrenal axis, or HPA axis (one of the body's four neuroendocrine systems, playing a central role in regulating portions of the metabolic, cardiovascular, immune, reproductive and central nervous systems), skin atrophy (thinning), striae (stretch marks), and telangiectasias (spider veins), among other side effects. Furthermore, some of these side effects are irreversible, persisting even after therapy is discontinued. Based on market research and our internal estimates, we estimate the population of patients treated with prescribed topical therapies in the United States is approximately 2.5 million patients and 5.4 million patients for psoriasis and atopic dermatitis, respectively. We estimate our addressable market opportunity, which focuses on patients treated by dermatologists with topical therapies, for each of psoriasis and atopic dermatitis is 2.0 million patients and 1.0 million patients, respectively.

In order to capitalize on our opportunity, we have assembled a management team with deep development, formulation and commercialization expertise for dermatology products. Our management team has held key roles in numerous biotechnology and pharmaceutical companies with a dermatology focus, including Pfizer Inc., Amgen Inc., Gilead Sciences, Inc., Kythera Biopharmaceuticals, Inc., Verrica Pharmaceuticals Inc., and Fougera Pharmaceuticals Inc. Through these roles, our management team was integrally involved in the development, approval and/or commercialization of more than thirty FDA-approved products (including eighteen topical products) such as Enbrel, Jublia, CeraVe, Aczone, and Xeljanz. This extensive experience provides us with unique insights and capabilities in dermatology drug development and commercialization.

We are supported by our board of directors and scientific advisors, who have significant experience in dermatology as well as expertise in public companies and business development. Our key investors include funds managed by Bain Capital Life Sciences, BlackRock, Frazier Healthcare Partners, Goldman Sachs, HBM Healthcare Investments, Omega Funds, OrbiMed, Pivotal BioVentures, RA Capital, and Vivo Capital, among others.

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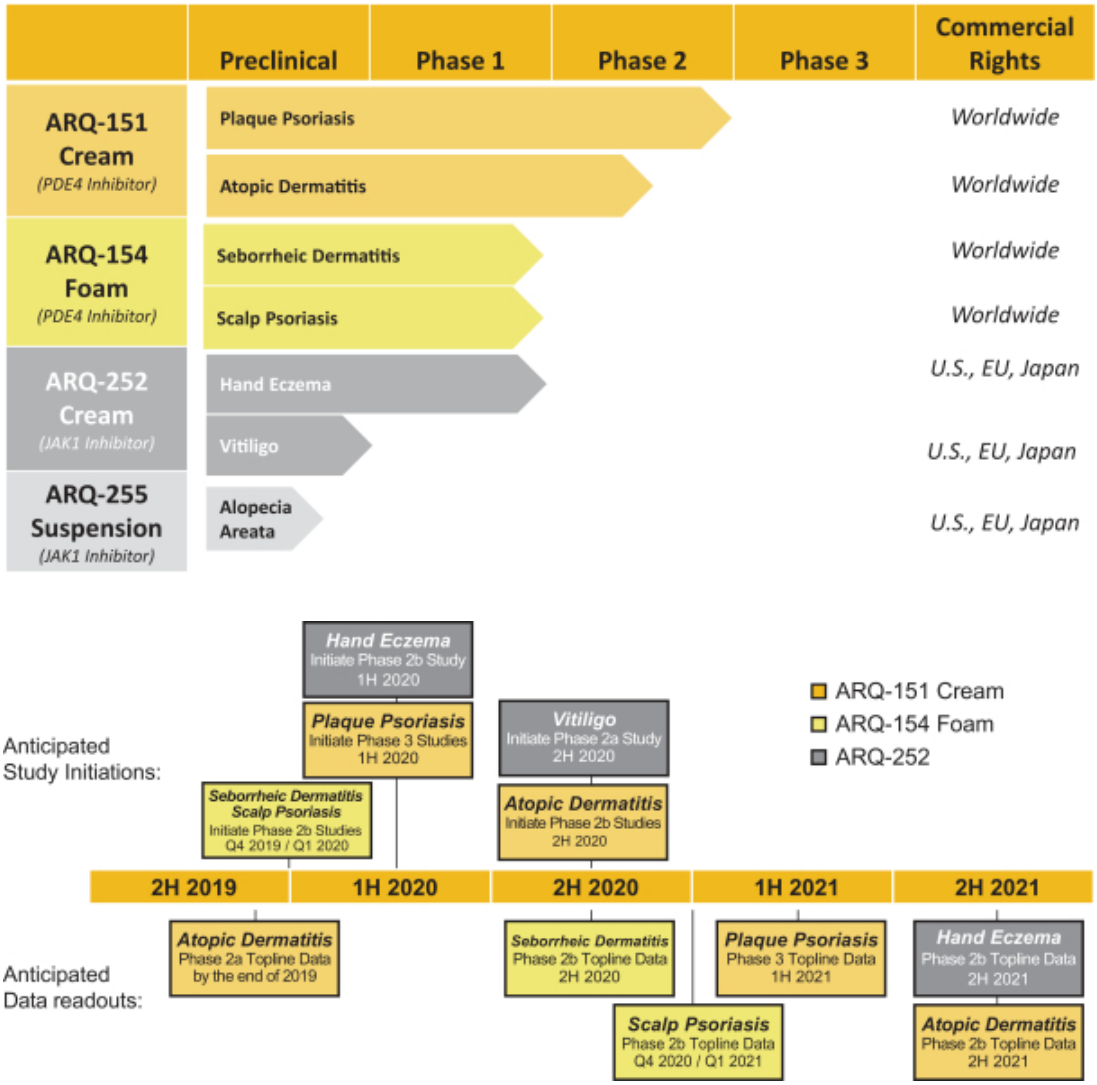
PURSUANT TO 17 C.F.R. SECTION 200.83**

Our Pipeline

The following charts summarize our product pipeline, including our lead product candidate, ARQ-151, and our upcoming anticipated milestones:



ARQ-151

Our lead product candidate, ARQ-151 is a topical cream containing roflumilast, a PDE4 inhibitor, that we are developing to treat plaque psoriasis, including intertriginous psoriasis, and atopic dermatitis. Based on the clinical data we have generated to date, we believe ARQ-151 has the potential to offer symptomatic improvement similar to a high-potency steroid, a favorable tolerability profile, the ability to treat chronically, and little to none of the application site skin reactions associated with many existing treatments.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

In July 2018, we executed a licensing agreement with AstraZeneca AB, or the AstraZeneca License Agreement, for exclusive worldwide rights to roflumilast, the PDE4 inhibitor used as the active pharmaceutical ingredient in ARQ-151 as a topical product in humans solely for dermatological indications. We have built our own intellectual property portfolio around topical uses of roflumilast, with issued and pending formulation and pharmacokinetic patents/applications in the United States and other jurisdictions from four distinct patent families, which should provide us with exclusivity at least through 2037 for the formulation that is intended to be marketed.

Mechanism of Action and Differentiation

ARQ-151 is a topical cream formulation of roflumilast, a highly potent and selective PDE4 inhibitor. Roflumilast was approved in 2011 for systemic treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease, or COPD, in patients with associated chronic bronchitis in 2011, with an estimated aggregate usage of over 1.0 million patient years to date.

PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators, and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and COPD. PDE4 is an established biological target in dermatology. The FDA has approved a number of PDE4 inhibitors, including Eucrisa for the topical treatment of atopic dermatitis and Otezla for the systemic treatment of plaque psoriasis.

Roflumilast, the active component of ARQ-151, has demonstrated greater potency relative to the active ingredients in two approved PDE4 treatments based on IC50 values (the concentration at which a biologic target's activity is inhibited by 50% and a non-clinical measure of a drug's potency), and has not produced the harmful side effects frequently associated with other PDE4 treatments, such as the application site burning frequently associated with Eucrisa, or the gastro-intestinal side effects frequently associated with Otezla, an oral PDE4. Based on the potency of roflumilast and the clinical results of ARQ-151, as well as the prior failures of topical crisaborole (Eucrisa) and topical apremilast (Otezla) in psoriasis, we believe that it is likely that ARQ-151 will be the only topical PDE4 inhibitor approved for the treatment of psoriasis.

Clinical and Safety Data and Development Plan

Plaque Psoriasis

For our lead product candidate, ARQ-151, we have completed two randomized, double-blind, vehicle-controlled Phase 2 studies in plaque psoriasis, including a 331-patient multinational, multi-center Phase 2b study and an 89 patient multinational, multi-center Phase 2a study. Both studies have demonstrated significant reductions in the signs of plaque psoriasis and ARQ-151 has been well-tolerated in this population. In our Phase 2b study, ARQ-151 also demonstrated significant reductions in the signs of psoriatic plaques in the intertriginous regions, as well as favorable tolerability in those areas. We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, enrolling 333 patients to undergo 52 weeks of treatment, and expect to report topline data in the first half of 2021.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

The following table summarizes the results from our Phase 2b study of ARQ-151 in plaque psoriasis:

		Phase 2b (ARQ-151-201)			
	% of Patients	0.3% Dose (n = 109)	0.15% Dose (n = 113)*(a)*	Vehicle (n = 109)*(b)*	*p-value (0.3% vs. vehicle)*
Week 6	**% IGA of Clear or Almost Clear**	28.0	22.8	8.3	<0.001
Week 8	**% IGA Success***(c)*	32.2	24.5	9.8	*< 0.001*
	Mean % CFB in PASI	(53.7)	(53.5)	(18.8)	*< 0.001*
	% PASI-75	31.3	23.0	13.2	*0.002*
	% PASI-90	16.9	7.4	6.0	*0.015*
	% Intertriginous IGA Success*(d)*	87.1	60.9	36.1	*0.007*
	% WI-NRS (4 pt Δ)*(e)*	64.6	58.2	42.3	*0.01*
TEAEs	**% TEAE**	38.5	27.3	29.9	—
	% Tx-Related TEAE	6.4	2.7	6.5	—
	% SAE	0.9	0.9	1.9	—
	% D/C due to TEAE	0.9	0.0	1.9	—

The abbreviations used in this table include the following: Change from baseline, or CFB; Investigator's Global Assessment, or IGA, a 5-point scale for evaluating plaque psoriasis severity; Psoriasis Area and Severity Index, or PASI; Treatment-Emergent Adverse Events, or TEAE; Serious Adverse Events, or SAE; discontinuation, or D/C.

P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a 95% probability that the results did not occur by chance alone, and are generally considered statistically significant results.

(a) For safety analyses, n = 110.
(b) For safety analyses, n = 107.
(c) IGA Success was defined as IGA = 0 (clear) or 1 (almost clear) PLUS a 2 point change from baseline.
(d) Intertriginous IGA, or I-IGA, Success was defined as I-IGA = 0 (clear) or 1 (almost clear) PLUS a 2 point change from baseline. I-IGA Success analysis was performed in subjects with baseline I-IGA ≥ 2.
(e) Represents % of patients with baseline Worst Itch-Numerical Rating Scale, or WI-NRS, ≥ 6, who achieved at least a 4-point improvement on the WI-NRS.

Based on the clinical data we have generated to date, we believe that ARQ-151 is uniquely suited to address unmet needs in psoriasis and has the potential to treat this condition without the use of high-potency steroids, with a favorable tolerability profile, and with the ability to administer chronically and in all anatomical areas. After holding a positive End-of-Phase 2 Meeting with the FDA in October 2019, we intend to initiate a Phase 3 program for ARQ-151 in the first half of 2020, which will include two registrational Phase 3 studies in plaque psoriasis, including intertriginous psoriasis. We plan to develop ARQ-151 under the Section 505(b)(1) pathway for marketing approval.

Atopic Dermatitis

We have also completed one Phase 1 study of ARQ-151 in atopic dermatitis, in which 16 adults with mild to moderate atopic dermatitis covering 4% to 8% body surface area, or BSA, were treated once daily for 15 days with: (1) 0.15% ARQ-151 topical cream, or (2) 0.05% ARQ-151 topical cream. The study found that systemic exposure upon topical application of ARQ-151 at the same concentration and over the same BSA was similar in atopic dermatitis subjects and in psoriasis subjects. This suggests that the side effect profile and tolerability of ARQ-151 in atopic dermatitis may be similar to that seen in psoriasis. The mean percent BSA involvement decreased from 6.1% in the

0.15% group and 5.8% in the 0.05% group at baseline to 3.1% and 2.6%, respectively, at week 2, reflecting reductions of 49% and 55%. While there was no vehicle control in this study, we believe these results suggest that ARQ-151 may provide symptomatic improvement in the treatment of atopic dermatitis. We have completed enrollment of a Phase 2a study of ARQ-151 in atopic dermatitis, having enrolled 136 adolescents (ages 12 and above) and adults with atopic dermatitis. We expect to have topline results from this study in by the end of 2019. If successful, we plan to initiate a Phase 2b study in atopic dermatitis in the second half of 2020 with topline results in the second half of 2021.

ARQ-154

We are also developing ARQ-154, a foam formulation of ARQ-151, for treatment of seborrheic dermatitis and scalp psoriasis. We designed ARQ-154 as a topical foam version of ARQ-151 to overcome the challenges of delivering topical drugs in hair-bearing areas of the body. Based on the results of our Phase 2 studies with ARQ-151, we believe that ARQ-154 has the potential to show similar results for treatment of scalp psoriasis and seborrheic dermatitis. We plan to initiate Phase 2b studies for ARQ-154 in seborrheic dermatitis and scalp psoriasis in Q4 2019/Q1 2020. We plan to develop ARQ-154 under the Section 505(b)(1) pathway for marketing approval.

ARQ-252

ARQ-252 is a potent and highly selective topical small molecule inhibitor of JAK1 that we are developing for hand eczema and other inflammatory dermatoses. In January 2018, we executed an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd. of China, or Hengrui, for the active pharmaceutical ingredient in ARQ-252 for all topical dermatological uses in the United States, Europe and Japan. The Hengrui License Agreement includes an option to license composition of matter patents in the United States, and those patents extend to 2034 for the bisulfate form of the active ingredient. We believe there is the potential to obtain additional protection for ARQ-252 through possible future formulation patents and other intellectual property.

Mechanism of Action

Many inflammatory cytokines and other signaling molecules rely on the JAK pathway, and specifically JAK1, which plays a central role in immune system function. Inhibition of JAK1 has been shown to treat a range of inflammatory diseases, including rheumatoid arthritis, psoriasis, Crohn's disease, and eczema. We believe that due to its high selectivity for JAK1 over JAK2, ARQ-252 has the potential to treat inflammatory diseases without causing the hematopoietic adverse effects, such as anemia, thrombocytopenia, and neutropenia, associated with JAK2 inhibition.

Clinical Data and Development Plan

We intend to initiate a Phase 2b study in adult patients with hand eczema in the first half 2020, with topline data expected in the second half of 2021. We also plan to initiate a Phase 2a study in vitiligo in the second half of 2020. In mid-2019, Hengrui completed a Phase 2b study in rheumatoid arthritis that used the same active pharmaceutical ingredient as in ARQ-252 but dosed orally. The results confirmed that this active pharmaceutical ingredient is a highly potent inhibitor of JAK1 based on the drug's impact on rheumatoid arthritis, and was generally well tolerated at exposures well above those expected with topical administration of ARQ-252. We plan to develop ARQ-252 under the Section 505(b)(1) pathway for marketing approval.

ARQ-255

We believe that topical JAK inhibitor therapy for alopecia areata requires the drug to be delivered to the site of the inflammation, deep in the skin at the base (bulb) of the hair follicle. We have

formulation and preclinical efforts underway for ARQ -255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin to the postulated site of inflammation in alopecia areata. If those formulation efforts are successful, we plan to enter the clinic with ARQ-255 as a potential treatment for alopecia areata.

Our Competitive Strengths

Our competitive strengths are key differentiating factors that form the foundation of our business strategy. We believe that leveraging these strengths will allow us to realize our vision of becoming a leading dermatology company. Our competitive strengths include:

- ***Harnessing the benefits of clinically validated targets in dermatology.*** We are focused on identifying, developing and commercializing best-in-class molecules against biological targets that have been clinically demonstrated to directly affect dermatological diseases. We believe this approach enables us to advance potentially transformative treatments over shorter development timelines, at lower cost, and in a manner that improves their probability of technical success.
- ***Late-stage lead product candidate with a highly differentiated clinical profile.*** Our lead product candidate, ARQ-151, is a topical cream formulation of roflumilast, a highly potent and selective PDE4 inhibitor that was approved by the FDA for systemic treatment to prevent exacerbations of COPD in 2011. PDE4 inhibition is a well-established mechanism in dermatology, as supported by the PDE4 inhibitors approved by the FDA, including Eucrisa, for the topical treatment of atopic dermatitis and Otezla for the systemic treatment of plaque psoriasis. ARQ-151 has generated what we believe is promising data in multiple clinical trials to date. We expect to initiate Phase 3 clinical trials with ARQ-151 in plaque psoriasis in the first half of 2020, and have completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis. We also have completed enrollment of a Phase 2a study of ARQ-151 in atopic dermatitis, and expect to report topline results from this study by the end of 2019. We believe that ARQ-151 has the potential to offer physicians and patients a highly differentiated clinical profile to address the significant unmet need in the treatment of plaque psoriasis and atopic dermatitis.
- ***Diversified, multi-asset pipeline addressing major shortcomings of existing dermatologic treatments.*** In addition to ARQ-151, we are advancing a portfolio of topically-administered product candidates addressing multiple immuno-dermatological indications with significant market opportunities, including seborrheic dermatitis, scalp psoriasis, hand eczema, vitiligo, and alopecia areata. We plan to initiate Phase 2b trials in Q4 2019/Q1 2020 in seborrheic dermatitis and scalp psoriasis using ARQ-154, a foam formulation of ARQ-151, that is designed to overcome the challenges of delivering topical drugs in hair-bearing areas of the body. Additionally, with ARQ-252, a potent and highly selective topical JAK1 inhibitor, we plan to initiate a Phase 2b study in hand eczema in the first half of 2020 and a Phase 2a study in vitiligo in the second half of 2020. We also have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. We believe that due to their high selectivity for JAK1 over JAK2, ARQ-252 and ARQ-255 have the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition.
- ***Strong intellectual property.*** As of September 30, 2019, we own or have the option to exclusively license 15 issued or pending U.S. patents, 15 issued or pending foreign patents and three international applications filed under the Patent Cooperation Treaty, providing comprehensive protection for our product candidates. For ARQ-151 and ARQ-154, we have built our own intellectual property portfolio around topical uses of roflumilast, with issued and

pending formulation and pharmacokinetic patents/applications in the United States and other jurisdictions from four distinct patent families, which begin to expire in 2037. Our patent protection includes an option to exclusively license four issued U.S. patents and four issued foreign patents providing protection for the active ingredient in ARQ-252 and ARQ-255, which begin to expire in 2033 with potential additional protection through possible future formulation patents and other intellectual property.

- ***Proven leadership team with differentiated formulation expertise.*** Our management team has extensive expertise in the development and commercialization of dermatology products, having held key leadership roles at a number of leading dermatology companies and, that collectively, has successfully developed and/or commercialized more than thirty FDA-approved products. In addition, we have unique expertise with developing differentiated and proprietary topical formulations of compounds in order to optimize their tolerability and efficacy in dermatology applications. We believe that the breadth of experience and successful track record of our management team, combined with our broad network of established relationships with leaders in the industry and medical community, uniquely positions us to build a leading, fully-integrated dermatology company.

Our Strategy

Our strategy is to leverage recent innovations in inflammation and immunology to identify molecules against validated biological targets in dermatology, to develop and commercialize best-in-class products that address significant unmet needs in immuno-dermatology. Key elements of our strategy include:

- ***Rapidly develop and commercialize our lead product candidate ARQ-151 for the treatment of patients with plaque psoriasis and atopic dermatitis.*** We plan to develop ARQ-151 for the treatment of plaque psoriasis and atopic dermatitis. Based on the clinical data generated to date, we believe ARQ-151 has the potential to be the best-in-class non-steroidal topical treatment with symptomatic improvement similar to high-potency steroids while potentially delivering a low risk of side effects and a favorable tolerability profile that enables chronic administration, including for pediatric patients. We plan to initiate Phase 3 studies in plaque psoriasis in the first half of 2020 and expect to report Phase 2a topline data on the use of ARQ-151 in atopic dermatitis by the end of 2019. In addition, we completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis and expect to report topline data in the first half of 2021.
- ***Expand our addressable market with ARQ-154.*** ARQ-154 is a foam formulation of ARQ-151 for the treatment of scalp psoriasis and seborrheic dermatitis that we developed to treat hair-bearing areas of the body like the scalp where a cream is not suitable. Based on the results of our Phase 2 studies with ARQ-151, we believe ARQ-154 has the potential to offer patients symptomatic improvement similar to high-potency steroids in scalp psoriasis and may be superior to standard of care treatments for seborrheic dermatitis, while potentially maintaining a low risk of side effects and favorable tolerability.
- ***Continue to innovate and develop our product pipeline of therapeutics which we believe have the potential to be best-in-class in immuno-dermatology.*** We plan to develop ARQ-252, a JAK1 inhibitor with a high relative selectivity to JAK1 over JAK2, for the treatment of hand eczema and potentially vitiligo and alopecia areata. Given its high relative selectivity to JAK1 over JAK2, we believe ARQ-252 has the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition, giving it the potential to be best-in-class. We plan to initiate our Phase 2b study in hand eczema in the first half of 2020 and our Phase 2a study in vitiligo in the second half of 2020. Additionally, we have

formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

- ***Establish an integrated development and commercial organization*.** We believe the concentrated prescriber base of the U.S. dermatology segment provides us with the opportunity to build a fully integrated commercial organization and targeted sales force for the commercialization of our product candidates among dermatology specialists. To further enhance the value of our product candidates, we will selectively seek partners to commercialize our products outside of the dermatology specialist segment, and to develop and commercialize our products outside of the U.S. market.
- ***Evaluate strategic opportunities to in-license best-in-class dermatology assets consistent with our core strategy.*** Leveraging our deep expertise in identifying promising drug candidates in dermatology, we will continue to seek best-in-class assets across treatment modalities directed against validated targets. We will continue to explore opportunities to in-license assets and develop them to address unmet medical needs in dermatology.

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Our Product Candidates

Product Candidate	Mechanism of Action	Formulation	Indication	Potential Clinical Profile Differentiation	Primary U.S. Addressable Market Opportunity
ARQ-151	PDE4 Inhibitor	Topical Cream	Psoriasis Atopic Dermatitis	• Non-steroidal topical treatment with similar symptomatic improvement as high-potency steroids • Low risk of side effects and favorable tolerability to enable chronic administration, including for pediatric patients • Able to be used on any part of the body, including sensitive or difficult-to-treat areas, such as the face and intertriginous regions	• Approximately 2.0 million patients treated by dermatologists with topical therapies • Approximately 1.0 million patients treated by dermatologists with topical therapies
ARQ-154	PDE4 Inhibitor	Topical Foam	Seborrheic Dermatitis Scalp Psoriasis	• Non-steroidal topical treatment with similar symptomatic improvement as high-potency steroids • Low risk of side effects and favorable tolerability to enable chronic administration • Designed for use in the peri-ocular area with low risk of side effects, and in a formulation that is convenient to use on hair-bearing areas of the scalp	• Approximately 360,000 patients treated by dermatologists that have an inadequate response to existing Rx therapies • Approximately 850,000 patients treated by dermatologists with topical prescription therapies
ARQ-252	JAK1 Inhibitor	Topical Cream	Hand Eczema Vitiligo	• Non-steroidal topical treatment with similar symptomatic improvement as high-potency steroids • Due to high selectivity for JAK1, uniquely positioned to treat skin inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition	• Approximately 7.0 million patients • Approximately 2.6 million patients
ARQ-255	JAK1 Inhibitor	Topical Suspension	Alopecia Areata	• In addition to the ARQ-252 profile, deep dermal delivery of the JAK1 inhibitor to the site of inflammation causing alopecia areata.	• Approximately 6.2 million patients

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ARQ-151

Overview

Our lead product candidate, ARQ-151, is a topical cream containing roflumilast, a PDE4 inhibitor, that potentially offers symptomatic improvement similar to a high-potency steroid, a favorable tolerability profile, the ability to treat chronically, and little to none of the application site reactions associated with many existing treatments. We are currently developing ARQ-151 for plaque psoriasis, including intertriginous psoriasis, as well as atopic dermatitis. We have successfully completed a Phase 2b study of ARQ-151 in plaque psoriasis. We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, and expect to report topline data in the first half of 2021. After holding a positive End-of-Phase 2 Meeting with the FDA in October 2019, we plan to initiate Phase 3 studies in plaque psoriasis in the first half of 2020, with topline data from the long-term safety study and the Phase 3 studies expected in the first half of 2021. We also have completed enrollment of a Phase 2a study of ARQ-151 in atopic dermatitis, and expect to report topline results from this study by the end of 2019.

In July 2018, we executed a licensing agreement with AstraZeneca AB for exclusive worldwide rights to roflumilast, the PDE4 inhibitor used as the active pharmaceutical ingredient in ARQ-151 and ARQ-154, as a topical product in humans solely for dermatological indications. We have built our own intellectual property portfolio around topical uses of roflumilast, with issued and pending formulation and pharmacokinetic patents/applications in the United States and other jurisdictions from four distinct patent families, which should provide us with exclusivity for the formulation that is intended to be marketed at least through 2037. We estimate there are a total of 8.6 million patients suffering from psoriasis and 19.2 million patients suffering from atopic dermatitis in the United States. Based on market research and our internal estimates, we estimate the population of patients treated with prescribed topical therapies in the United States is approximately 2.5 million patients and 5.4 million patients for psoriasis and atopic dermatitis, respectively. We estimate our primary addressable market opportunity, which focuses on patients treated by dermatologists with topical therapies, for each of psoriasis and atopic dermatitis is 2.0 million patients and 1.0 million patients, respectively.

Mechanism of Action

PDE4 is an intracellular enzyme that regulates the production of pro-inflammatory and anti-inflammatory cytokines and cell proliferation via the degradation of cyclic AMP, or cAMP. PDE4 inhibition can inhibit inflammatory responses through, among other pathways, reductions in TNF-a, interferon-g, interleukin-4 (IL-4), interleukin-13 (IL-13), interleukin-17 (IL-17) and interleukin-23 (IL-23). Moreover, PDE4 inhibition can also promote the barrier function of keratinocytes via suppression of inflammatory mediator production. PDE4 has been implicated in a wide range of inflammatory diseases including asthma, COPD, psoriasis, atopic dermatitis, inflammatory bowel diseases, rheumatoid arthritis and lupus.

Product Profile & Differentiation

ARQ-151 is a topical cream formulation of roflumilast, a highly potent and selective PDE4 inhibitor that was approved by the FDA for systemic treatment to reduce of the risk of exacerbations of COPD in 2011. ARQ-151 is designed for simple once-a-day application for chronic use, does not to burn or sting on application, and can be used on any part of the body, including sensitive or difficult-to-treat areas, such as the face and intertriginous regions. It quickly and easily rubs into the skin without leaving a greasy residue, and does not stain clothing or bedding or have an unpleasant smell.

The table below shows the relative potency of roflumilast compared to the active ingredients in two FDA-approved PDE4 inhibitors, demonstrating a potency advantage of roflumilast of approximately 25x to in excess of 300x.

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PDE4 Inhibitor Potency

A lower IC50 value (the concentration at which a biologic target's activity is inhibited by 50% and a non-clinical measure of a drug's potency), indicates a higher affinity of binding to the various PDE4 isoforms and thus greater potency.

IC50 (nM)	PDE4B	PDE4A1A	PDE4B1	PDE4C1	PDE4D7
Roflumilast	0.47	0.33	0.28	0.95	0.53
Crisaborole (Eucrisa)	75	55	61	340	170
Apremilast (Otezla)	39	9	16	48	12

We believe ARQ-151 addresses major unmet needs in the treatment of plaque psoriasis and atopic dermatitis and, based on the clinical data generated to date, has the potential to offer symptomatic improvement similar to high-potency steroids, a low risk of side effects, a favorable tolerability profile to enable chronic administration in all anatomical areas, and a convenient and patient-friendly topical formulation.

Plaque Psoriasis

Psoriasis Background

Psoriasis is an immune disease that occurs in about two percent of adults in western countries, representing approximately 8.6 million patients in the United States. About 90% of cases are plaque psoriasis, which is characterized by "plaques", or raised, red areas of skin covered with a silver or white layer of dead skin cells referred to as "scale" (see figures below). Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and the plaques are often itchy and sometimes painful. At least 40% of plaque psoriasis patients have plaques on their scalp, which presents a challenge for drug delivery, as the creams and ointments typically used to treat psoriasis on other body areas are not appropriate for use on the scalp. About 15% of plaque psoriasis patients have plaques in their intertriginous regions, which are particularly difficult to treat because these areas tend to have thinner, more easily irritated skin, and are more prone to steroid-related side effects, especially skin atrophy (thinning), striae (stretch marks) or telangiectasia (spider veins). Approximately 10% of plaque psoriasis patients have plaques on their face, which similarly has thinner, more easily irritated skin and greater vulnerability to side effects. Treatment of facial plaques is also complicated by proximity to the eyes, and the consequent heightened safety concerns, specifically increased risk for development of cataracts and glaucoma due to steroid exposure. One in three plaque psoriasis patients has plaques on their elbows and knees, which are frequently treatment resistant. Even with biologic therapies, plaques on the elbows and knees are often the last areas to resolve.

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Psoriasis patients are generally characterized as mild, moderate, or severe, with approximately 75% experiencing a mild to moderate form of the disease.

Figures: Plaque Psoriasis
Source (right): DermNet

Pruritus or itching is a particularly common and bothersome symptom for patients. A recent chart review of U.S. psoriasis patients by Adelphi Group found nearly half of moderate to severe patients and one in five mild patients reported experiencing significant itching (as indicated by reports of at least a 4 on a 10-point scale) sometimes, usually or all of the time. Three quarters of moderate to severe patients with itch, and one third of mild patients with itch reported that the itching also disturbed their ability to sleep.

In addition to the direct clinical challenges of psoriasis, it has been documented that patients with plaque psoriasis suffer substantial psychosocial impacts from their disease, including: social stigmatization, feelings of rejection and shame, guilt, impaired sexual intimacy, discrimination in the workplace, difficulty finding employment or working outside the home, financial hardships, increased work absenteeism and reduced productivity. Patients with psoriasis also have a 50% greater chance of depression than the general population.

Current Psoriasis Treatment Landscape

The vast majority of psoriasis patients are treated with topical therapies, of which there have been no novel treatments approved in over 20 years. The Adelphi Group U.S. chart review discussed above found that 95% of all patients reviewed had received a topical treatment at some point in their therapy, 86% had received a topical as the first line therapy, and 71% continued to receive topical therapy, either alone or in combination with other treatments. Despite their widespread use, existing topical therapies all possess substantial shortcomings:

- ***Topical steroids***, especially the high-potency topical steroids generally used to treat psoriasis, are associated with HPA axis suppression, skin atrophy (thinning), striae (stretch marks), and telangiectasia (spider veins), among other side effects. Furthermore, some of these side effects are irreversible, persisting even after therapy is discontinued. Consequently, high-potency topical steroids are not recommended for chronic use, and physicians generally will not prescribe them for treatment on the face or in the intertriginous regions. For example, the label for clobetasol propionate, the most commonly used high-potency steroid, limits use to two consecutive weeks and use on the face or intertriginous regions is contraindicated.

- ***Vitamin D3 analogs*** such as calcipotriene, provide substantially less symptomatic improvement than high-potency steroids, and are frequently irritating. While they can be used chronically, tolerability issues with their use can be a challenge, and physicians generally will not prescribe them for use on the face or in the intertriginous regions.
- ***Vitamin D3/steroid combinations*** offer better symptomatic improvement than either of the two individual components alone, but still carry a risk of HPA axis suppression, and are limited in their duration of use. For example, Taclonex ointment is limited to 4 weeks of treatment.

Because high-potency steroids and combinations containing high-potency steroids provide robust symptomatic improvement for psoriasis patients, most physicians initiate treatment for nearly all patients on them. But due to the limitations on duration of treatment to between two and eight weeks, physicians are quickly confronted with a conundrum of how to manage their psoriasis patients chronically. Most will switch the patient to a low- to mid-potency steroid or to a vitamin D analog. These “step down” options provide less symptomatic improvement, and in the case of vitamin D, are often irritating. Also, rebound is a known challenge with steroids, where after steroid discontinuation, the psoriasis returns even worse than it was before steroid treatment was initiated. Thus, patients are constantly cycling between short courses of high-potency steroids and “step down” maintenance treatments.

While biologic therapies, including drugs such as Enbrel, Cosentyx, Humira, and Stelara, are available for treatment, their use remains highly restricted. In the United States, less than 20% of moderate-to-severe psoriasis patients, equivalent to 6% of all psoriasis patients, are on biologic therapy. The uptake of biologics has remained limited due to multiple factors, including the fact that they are indicated only for use in moderate to severe patients, their high cost, which can be as much as $60,000 per year, consequent reimbursement and access restrictions, frequent high patient co-pays, perceived risk of side effects, and patient fear of injection.

Non-biologic systemic therapy options for psoriasis exist, but their use is also limited, according to Decision Resources Group, representing approximately 8% of patients worldwide, and 13% of patients in the United States. Methotrexate remains the most widely used systemic therapy, although its use continues to decline due to concerns about side effects and mandatory routine monitoring. Apremilast (Otezla), an oral PDE4 inhibitor, is another systemic option, but although it generated more than $1 billion in sales in all indications in 2018, it has only achieved 1.2% patient share in psoriasis due to limitations on its use to moderate-to-severe patients, modest symptomatic improvement, and frequent adverse events, or AEs.

Due to the shortcomings of existing topical therapies and the lack of options providing robust symptomatic improvement with chronic treatment, as well as the inherent challenges of treating psoriasis, the majority of patients continue to suffer from symptoms even when on treatment. Therefore, there remains a need for a non-steroidal topical treatment that is as effective as high-potency steroids, that can be used chronically, has a low risk of side effects and is well tolerated, and that can be used on all anatomical areas.

Atopic Dermatitis

Atopic Dermatitis Background

Atopic dermatitis is the most common type of eczema, occurring in approximately 6% of the population, representing approximately 19.2 million patients in the United States. Disease onset is most common by 5 years of age, and we estimate that approximately 60% of patients suffering from atopic dermatitis are pediatric patients. Atopic dermatitis is the most common skin disease among children, affecting approximately 15% to 20% of children.

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Atopic dermatitis is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms and legs, and the rash can cover significant areas of the body (see figures below), in some cases half of the body or more. The rash causes significant pruritus (itching), which can lead to damage caused by scratching or rubbing and perpetuating an 'itch-scratch' cycle.

Figures: Atopic Dermatitis Lesions
Source: DermNet

Given most of the patients are pediatric, safety and tolerability of atopic dermatitis treatments is paramount and explains the predominance of topical treatments. Atopic dermatitis imposes a substantial burden on both the patient and, particularly in the case of pediatric patients, the parents and family. Pediatric patients with atopic dermatitis can suffer from sleep disturbances, behavioral problems, irritability, crying, interference with normal childhood activities, and social functioning. Parents and families of pediatric patients with atopic dermatitis can also be impacted by a lack of sleep, emotional distress due to their child's suffering, and added workload caring for the atopic dermatitis patient. Adults with atopic dermatitis also frequently suffer from sleep disturbances, emotional impacts, and impaired social functioning. Adults with atopic dermatitis also appear to be at a significantly increased risk of anxiety, depression, and suicidal ideation compared to the general population.

Current Atopic Dermatitis Treatment Landscape

The vast majority of atopic dermatitis patients are being treated with topical therapies, particularly low- to mid-potency topical steroids and topical calcineurin inhibitors, or TCIs, and these two classes of drugs constituted 50% of atopic dermatitis prescription sales in 2017. While topical steroids are commonly used in atopic dermatitis, they are infrequently prescribed in patients with atopic dermatitis on the face or diaper/groin area. In lieu of steroids, or in response to parental concerns about steroid use, physicians frequently prescribe TCIs in patients with atopic dermatitis, especially for patients with lesions on the face or diaper/groin area. Biologic use for atopic dermatitis is currently limited. Dupixent, approved in early 2017, is the first biologic for atopic dermatitis for the treatment of adults and adolescents ages 12 and above with moderate-to-severe atopic dermatitis. Dupixent generated almost $900 million in net sales in 2018. Despite these impressive sales results, Dupixent was used in less than 1% of atopic dermatitis patients.

Despite their widespread use, existing topical therapies for atopic dermatitis all possess substantial shortcomings:

- ***Topical steroids*** pose a particular concern in pediatric patients due to the risk of systemic absorption, and the consequent risk of HPA axis suppression and potential developmental problems. Consequently, chronic use of topical steroids in atopic dermatitis patients is generally avoided. Many physicians are also reluctant to use steroids to treat atopic dermatitis on the face due to the increased risk of glaucoma and cataracts, or the diaper/groin region due to risk of skin thinning. There is also considerable concern among many parents about treating their children with steroids, which can be an obstacle to treatment for physicians.
- ***Topical calcineurin inhibitors*** are generally seen as providing less symptomatic improvement than topical steroids and are also associated with some application site burning. Probably most significant, in 2005 the FDA placed a boxed warning on the labels of both TCIs regarding a potential increased risk of cancers, especially lymphomas, associated with their use. While some experts have expressed skepticism over the warning, TCI sales dropped 30% the year after the boxed warning and have not recovered since.
- ***Eucrisa*** is a topical non-steroidal PDE4 inhibitor approved by the FDA in 2016. Despite initial interest among the physician community to adopt the product, its growth has been hampered by modest symptomatic improvement, frequent occurrences of application site burning, and disadvantaged reimbursement status compared to other atopic dermatitis treatments.

Physicians are dissatisfied with current treatments due to overall suboptimal symptomatic improvement, ability to control itching, and impact on patient/parent quality of life. Patients with, or parents of patients with, atopic dermatitis are dissatisfied with overall suboptimal symptomatic improvement, sustained symptomatic improvement over time, and the inconvenience of many of the topical treatments, including the greasy residue, the amount of time required to apply, and the general messiness of treatments.

Therefore, there remains a need for a non-steroidal topical treatment that provides more symptomatic improvement than current topical treatments, has a low risk of side effects, is well tolerated, and can be used chronically in pediatric patients and on all areas of the body.

Our Market Opportunity

Plaque Psoriasis

The sales of prescription treatments for psoriasis are large and growing rapidly. According to Decision Resources Group, the worldwide market for psoriasis will grow from $14.5 billion in 2018 (of which $12.2 billion was in the United States) to $22.7 billion in 2027, representing a 5% CAGR. The vast majority of prescription psoriasis sales are for biologic therapies, including drugs such as Enbrel, Cosentyx, Humira, and Stelara, which in 2018 represented $12.1 billion (83%) of all worldwide sales and 85% of U.S. sales.

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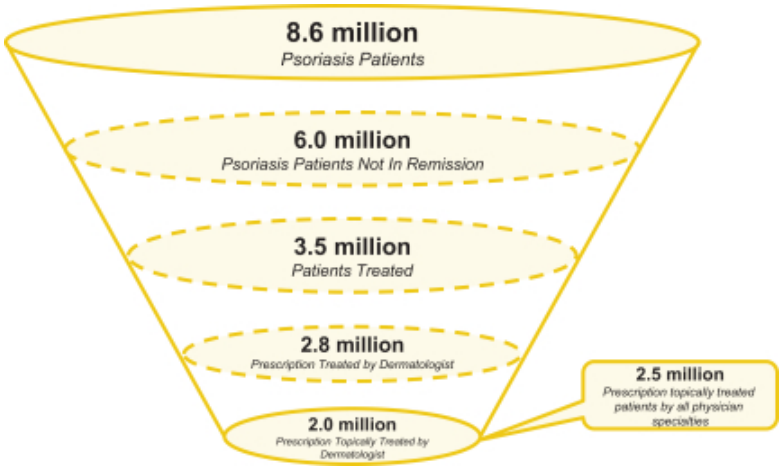
We believe there is a significant market opportunity for us to capture within plaque psoriasis. As depicted below, we estimate there are approximately 8.6 million psoriasis patients in the United States, of which approximately 6.0 million patients are not in remission and 3.5 million are seeking some form of treatment for the disease, of which approximately 82% are treated by dermatologists. We estimate that in the United States, 2.5 million patients are treated with prescription topical therapies, of which 2.0 million patients are treated with topical prescriptions by a dermatologist.



Atopic Dermatitis

While the current sales of prescription treatments for atopic dermatitis are considerably smaller than that for psoriasis, they are similarly expected to grow rapidly with the emergence of newer and better therapies. According to Decision Resources Group, the worldwide market in 2017 was $1.4 billion, but is expected to grow to $23 billion by 2027, representing a 32% CAGR.

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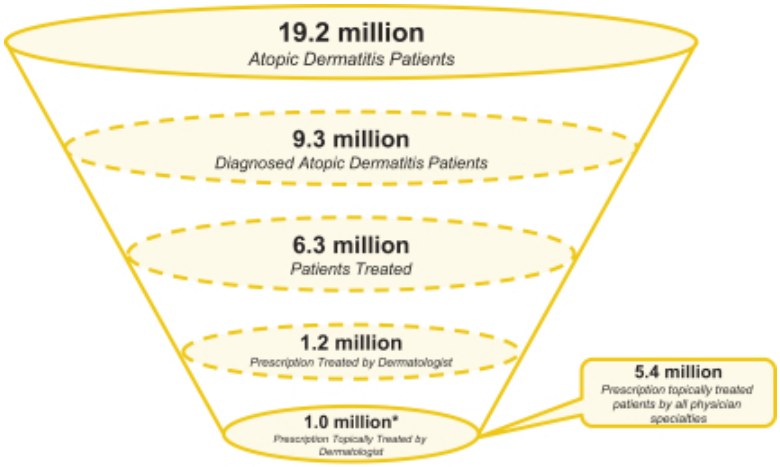
We believe there is a significant market opportunity for us to capture within atopic dermatitis. As depicted below, we estimate there are approximately 19.2 million atopic dermatitis patients in the United States, of which 9.3 million patients are diagnosed with atopic dermatitis. We estimate approximately 6.3 million atopic dermatitis patients are treated, of which 1.2 million patients are treated by dermatologists. We estimate that in the United States, 5.4 million patients are treated with prescription topical therapies, of which 1.0 million are treated with topical prescriptions by a dermatologist.



* Based on the percentage of pediatric patients with atopic dermatitis treated with topical prescriptions from dermatologists. A majority of patients suffering from atopic dermatitis are pediatric patients.

We believe ARQ-151 and ARQ-154 have the potential to address the limitations of current treatments for plaque psoriasis and atopic dermatitis.

ARQ-151 Clinical Development

Indication	Study Name	Phase	Number of Patients	Status
Plaque Psoriasis	151-101	Phase 1/2a	89	Completed
	151-201	Phase 2b	331	Completed
	151-202	Phase 2b	333	Ongoing
	151-301	Phase 3	~ 400 (Expected)	Upcoming
	151-302	Phase 3	~ 400 (Expected)	Upcoming
	151-306	Phase 3	~ 250 (Expected)	Upcoming
Atopic Dermatitis	151-102	Phase 1	16	Completed
	151-212	Phase 2a	136	Ongoing

We have completed two Phase 2 clinical trials evaluating ARQ-151 in adults with plaque psoriasis, and a Phase 1 clinical trial evaluating the pharmacokinetics of ARQ-151 in adults with atopic dermatitis. Two Phase 2 clinical trials are currently ongoing, one in plaque psoriasis and one in atopic dermatitis, and we expect to initiate Phase 3 plaque psoriasis studies in the first half of 2020.

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Plaque Psoriasis

Completed Trials

ARQ-151-201 (Phase 2b Study)

The most recent study conducted with ARQ-151 was a multi-center, multi-national, double-blind, vehicle-controlled Phase 2b study, in which 331 adults with plaque psoriasis covering between 2% and 20% BSA were randomized to receive 12 weeks of: (1) ARQ-151 0.3% topical cream, (2) ARQ-151 0.15% topical cream, or (3) matching vehicle. At the end of the 12-week treatment period, patients were eligible to roll over into our ARQ-151-202 open label extension study for an additional 52 weeks. Completion rates for the study were 93.6% in the ARQ-151 0.3% arm, 92.0% in the ARQ-151 0.15% arm, and 78.9% in the vehicle arm.

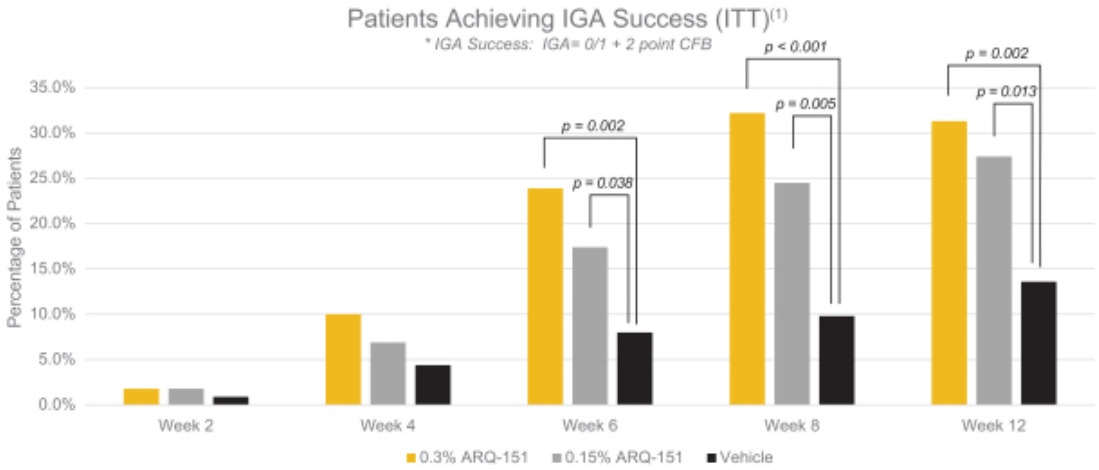
Primary Endpoint

The primary efficacy endpoint of our Phase 2b study was the percentage of subjects attaining a score of “clear” or “almost clear” on the IGA scale at week 6.

Both ARQ-151 0.3% and ARQ-151 0.15% separated from vehicle with statistical significance on the primary endpoint of percentage of patients achieving an IGA of “clear” or “almost clear” at week 6, with 28.0% of patients treated with ARQ-151 0.3% and 22.8% of patients treated with ARQ-151 0.15% achieving “clear” or “almost clear”, compared to 8.3% treated with vehicle (ARQ-151 0.3%: $p < 0.001$; ARQ-151 0.15%: $p = 0.004$).

Key Secondary Endpoint

The likely registrational endpoint for any topical psoriasis product is “IGA Success”, which is the percentage of patients attaining an IGA score of “clear” or “almost clear” PLUS a 2-grade improvement from baseline on the 5-point IGA scale. The results for this endpoint from the Phase 2b plaque psoriasis study are shown in the graph below:



(1) The intention to treat, or ITT, population includes all randomized patients. This clinical trial study population is intended to represent suitable patients and to be reflective of what might be seen if the treatment was used in clinical practice.

As shown in the graph above, both ARQ-151 0.3% and ARQ-151 0.15% separated from vehicle and demonstrated statistical significance on the percentage of patients achieving IGA Success at 8

weeks, with 32.2% of patients treated with ARQ-151 0.3% and 24.5% of patients treated with ARQ-151 0.15% achieving IGA Success, compared to 9.8% treated with vehicle.

Additional Secondary Endpoints

Additional secondary endpoints for our Phase 2b study included:

- The percentage of patients attaining a 75% or 90% reduction from baseline on their PASI score (PASI-75 and PASI-90) at weeks 4, 6, 8 and 12 compared to baseline;
- Among subjects with plaques in their intertriginous regions, an I-IGA of “clear” or “almost clear” PLUS a 2-grade improvement from baseline at weeks 4, 6, 8 and 12.
- Among subjects with documented pruritus (itching) with a baseline WI-NRS pruritus score of $\geq$ 6, at least a 4-point reduction from baseline at weeks 4, 6, 8 and 12.
- The mean change from baseline on a Patient Reported Outcomes, or PRO, assessment called the Psoriasis Symptom Diary, or PSD, at weeks 4, 6, 8 and 12.

The figure below includes photographs that are representative of patients of our Phase 2b study:

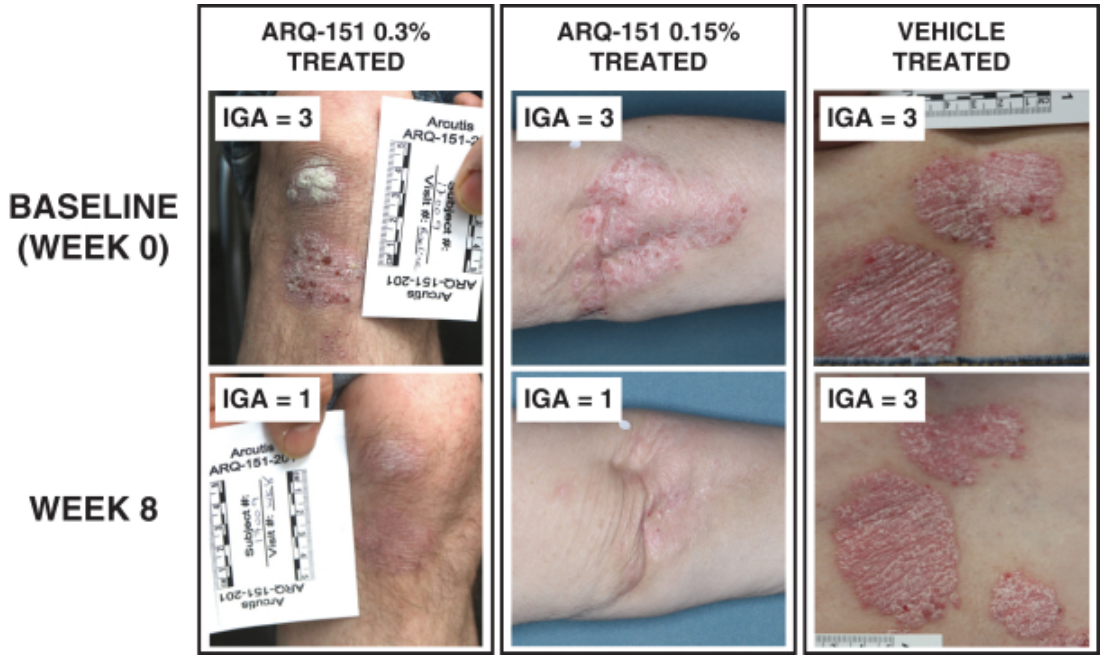


Figure: Representative Subject Photographs from Study ARQ-151-201

The upper row of photographs shows psoriatic plaques of individual study subjects in the ARQ-151 0.3% (left), ARQ-151 0.15% (middle) and vehicle (right) groups at baseline (Week 0). All 3 subjects were graded “moderate” (IGA 3) at baseline, as were 77.3% of all subjects enrolled in the study. The lower row of photographs shows those exact same psoriatic plaques of the exact same individual subjects after 8 weeks of treatment. The vehicle patient remained “moderate” (IGA 3). The subjects on both ARQ-151 0.15% and ARQ-151 0.3% achieved IGA Success – both subjects were IGA 1 at Week 8, improving 2 points from baseline. These two subjects are representative of the patients achieving IGA Success in the study.

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In published data from third party clinical trials involving halobetasol and bethamethasone dipropionate (Class 1 ultra high- and high-potency steroids), halobetasol and betamethasone dipropionate demonstrated a mean IGA Success rate of 32.5% at 8 weeks. Based on a retrospective post-hoc cross-trial comparison that we compiled based on published data and our Phase 2b study, we believe that ARQ-151 is likely to demonstrate similar mean IGA Success to these Class 1 steroids. In data from our Phase 2b study of ARQ-151, ARQ-151 0.3% demonstrated an IGA Success rate of 32.2% at 8 weeks. The results of this retrospective post-hoc cross-trial comparison may not be directly comparable, as they are not from a single head-to-head clinical trial. Further, while we believe this data is useful in informing the design of future clinical trials and potential for ARQ-151, cross-trial comparisons involve the inherent bias of post-hoc manipulation of data and choice of analytical methods, as well as methodological issues surrounding heterogeneity among studies contributing to the analyses; therefore, it is important to view such results in light of the totality of all available information, such as individual study results on pre-specified analyses of endpoints. This cross-study comparison will not be used to support regulatory filings for ARQ-151.

The chart below shows a comparison of data across these separate clinical trials.

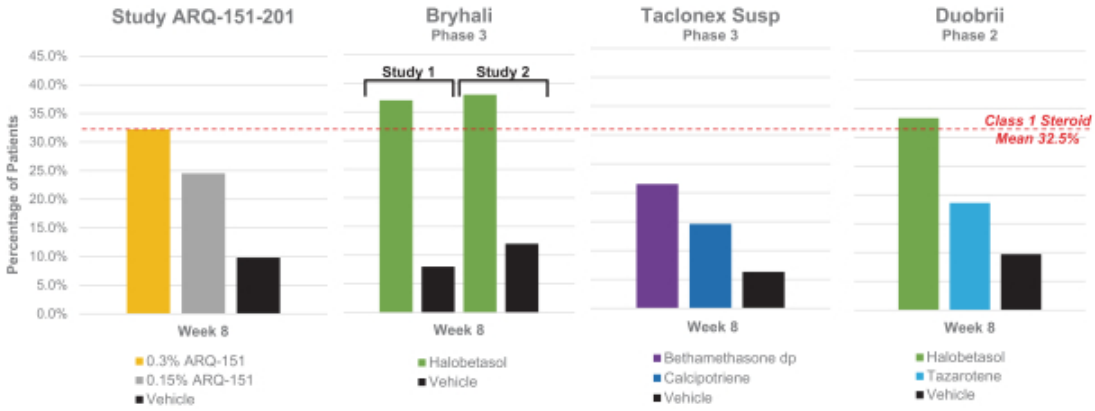

Figure: Comparison of IGA Success Rates Across Topical Psoriasis Trials

In our Phase 2b study, ARQ-151 0.3% also demonstrated promising results, based on percentage of patients achieving PASI-75 (31.3% in patients with moderate-to-severe psoriasis for ARQ-151 0.3% at week 8). Additionally, patients did not experience the frequent gastrointestinal side effects reported with certain other treatments. For example, ARQ-151 0.3% reported rates of diarrhea and nausea of 0.9% and 0.9%, respectively, in our Phase 2b study.

In Phase 3 studies, oral apremilast (Otezla) achieved response rates of 28.8% and 33.1% in their Phase 3 studies at 30 mg BID (twice a day) at week 16, compared to placebo response rates of 5.3% and 5.8%, in each trial, respectively. In Phase 3 studies, Otezla reported diarrhea and nausea rates of 18.8% and 15.7%, respectively.

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Both ARQ-151 0.3% and ARQ-151 0.15% demonstrated rapid onset of effect, with both doses statistically separating from vehicle as early as week 2 on mean percent CFB in PASI. The chart below shows mean percent CFB in PASI over the course of the study.

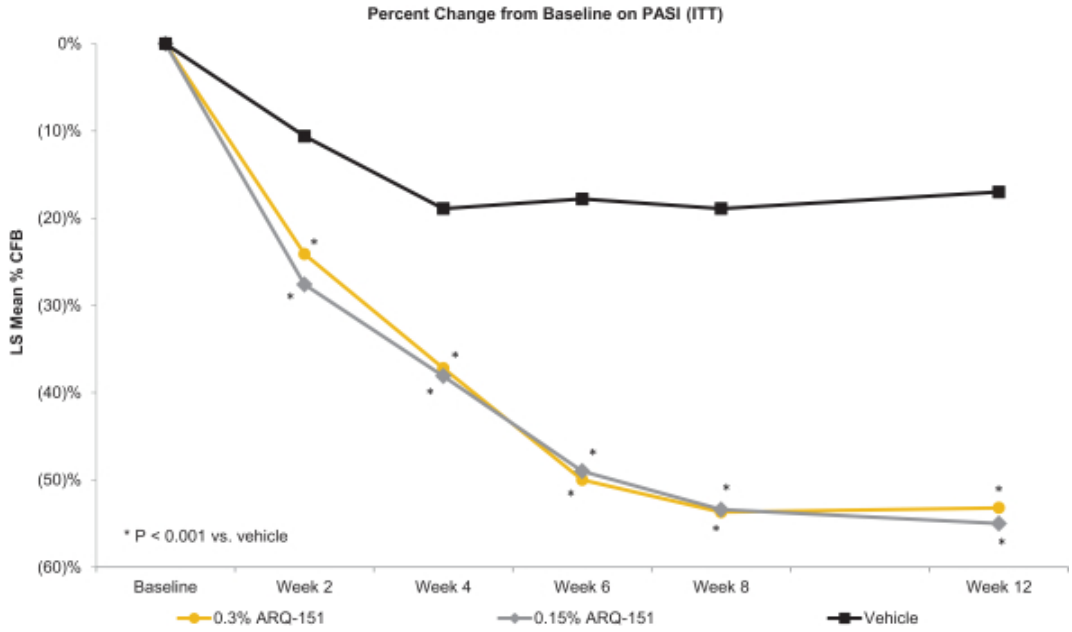

Figure: Percent Change from Baseline on PASI in Study ARQ-151-201

Additionally, statistically significantly more patients treated with ARQ-151 0.3% achieved a 75% improvement in PASI score (PASI-75) at 8 weeks than patients treated with vehicle (31.3% on ARQ-151 0.3% versus 13.2% on vehicle, p = 0.002), and more patients treated with ARQ-151 0.3% achieved a 90% improvement in PASI score (PASI-90) at 8 weeks than patients treated with vehicle (16.9% on ARQ-151 0.3% versus 6.0% on vehicle, p = 0.015).

As noted earlier, psoriatic plaques in the intertriginous regions are particularly challenging to treat. In this study, ARQ-151 demonstrated very strong results in the treatment of intertriginous plaques. In fact, 88.5% of patients treated with ARQ-151 0.3% who had intertriginous plaques at baseline achieved an I-IGA of “clear” (I-IGA = 0) by week 8, and 44.6% of patients treated with ARQ-151 0.15% who had intertriginous plaques at baseline achieved an I-IGA of “clear” (I-IGA = 0) by week 8 compared to 30.6% of vehicle patients achieving an I-IGA of “clear” (I-IGA = 0) by week 8 (p = 0.003).

Plaque psoriasis patients suffer from a number of symptoms associated with their disease, including itching, burning, stinging, skin cracking, and pain, in addition to the thickened, red and scaly plaques that are the hallmark of the disease. In Study ARQ-151-201, patients were asked to evaluate these symptoms using the PSD, a validated psoriasis PRO. Both doses of ARQ-151 demonstrated statistically significant (ARQ-151 0.3%: p<0.001; ARQ-151 0.15%: p<0.001) reductions in the total PSD score compared to vehicle at week 8, with statistical separation at week 2 (ARQ-151 0.15%) or week 4 (ARQ-151 0.3%). ARQ-151 0.3% also statistically separated from vehicle in reductions of itch as measured by WI-NRS, with 32.9% of patients with significant itching (baseline WI-NRS $\geq$ 6) treated with ARQ-151 0.3% experiencing at least a 40% reduction in their WI-NRS score at week 2 (p = 0.034), compared to 28.4% of patients treated with ARQ-151 0.15% and 16.7% of patients treated

with vehicle. At week 8, 64.6% of patients with significant itching (baseline WI-NRS > 6) treated with ARQ-151 0.3% experienced at least a 40% reduction in their WI-NRS score at week 8, compared to 58.2% of patients treated with ARQ-151 0.15% and 42.3% treated with vehicle.

Safety

In Study ARQ-151-201, ARQ-151 was well-tolerated by the subject population. The table below summarizes TEAEs in the study.

Table: Treatment-Emergent Adverse Events in ARQ-151-201

	ARQ-151 Cr 0.3% (N=109)	ARQ-151 Cr 0.15% (N=110)	Vehicle (N=107)
Subjects with any TEAE	42 (38.5%)	30 (27.3%)	32 (29.9%)
Number of TEAEs	85	51	47
Subjects with any Tx-Related TEAE	7 (6.4%)	3 (2.7%)	7 (6.5%)
Number of Related TEAEs	15	3	8
Subjects with any SAE	1 (0.9%)(a)	1 (0.9%)(b)	2 (1.9%)(c)
Number of SAEs	1	1	2
Subjects who discontinued Study Drug due to AE	1 (0.9%)	0	3 (2.8%)
Subjects who discontinued Study due to AE	1 (0.9%)(d)	0	2 (1.9%)(e)

(a) One subject in the ARQ-151 0.3% group experienced worsening of chest pain. The subject had a history of cardiovascular disease, and the investigator deemed the AE not to be treatment related.
(b) One subject in the ARQ-151 0.15% group developed a 1.4 millimeter deep non-ulcerated Melanoma. The melanoma was not an area of treatment, and the investigator deemed the AE not to be treatment related.
(c) One subject in the Vehicle group experienced an Acute Infarction of the Left Basal Ganglia deemed not to be treatment related by the investigator; another subject in the Vehicle group experienced a Spontaneous Miscarriage, deemed to be possibly treatment related by the investigator.
(d) One subject in the ARQ-151 0.3% group discontinued from the study on day 17 due to an adverse event of "psoriasis".
(e) Two subjects in the Vehicle group discontinued from the study due to AEs: one subject had an adverse event of "mood swings", the other subject had an adverse event of "contact dermatitis".

The incidence of AEs of special interest, such as the application site adverse reactions that are commonly associated with many other topical psoriasis treatments or the gastrointestinal side effects commonly seen with oral administration of roflumilast or other oral PDE4 inhibitors, was also low throughout this study:

- There was no evidence of burning or stinging at the site of application, as judged by either study subjects or investigators.
- Rates of gastrointestinal AEs were low and balanced across groups (ARQ-151 0.3% = 3.6%; ARQ-151 0.15% = 1.8%; Vehicle = 1.9%), none of those occurring in active-treated subjects led to study discontinuation, and only one subject experienced an AE (frequent bowel movements) which was deemed by the investigator to be likely, possibly, or probably related to treatment.
- Rates of psychiatric AEs were also low and balanced across groups (ARQ-151 0.3% = 2.8%; ARQ-151 0.15% = 1.8%; Vehicle = 2.8%), and none of those that occurred in active-treated subjects led to study discontinuation.
- Weight change during the study was uncommon, with weight loss of > 5% balanced across treatment groups, comparable rates of weight loss > 5% and weight gain > 5%, and no instances of weight loss > 10%.

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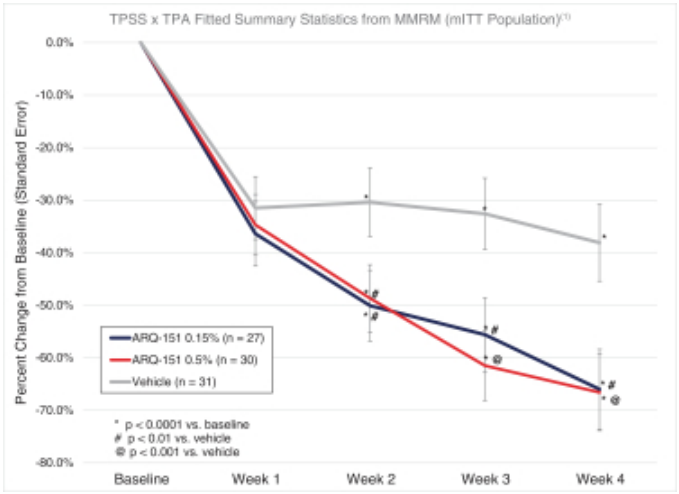
ARQ-151-101 (Phase 1/2a Study)

We earlier conducted a multi-center, multi-national, double-blind, vehicle-controlled Phase 1/2a study of ARQ-151, in which 89 adults with plaque psoriasis were randomized to receive 4 weeks of: (1) 0.5% ARQ-151 topical cream, (2) 0.15% ARQ-151 topical cream, or (3) matching vehicle. Patients applied test article once daily to between one and three "target plaques" totaling no more than 5% BSA. The primary efficacy endpoint was the change from baseline in the product of the TPSS, measuring redness, thickness, and scaling of a target plaque, and the TPA of the target plaque(s). The results for this endpoint are shown in the following chart:



(1) Product of Target Plaque Severity Score, or TPSS, and Target Plaque Area, or TPA, fitted summary statistics from Mixed effect Model Repeat Measurement (modified ITT population).

Figure: Improvement in Plaque Psoriasis by ARQ-151 in Study ARQ-151-101

In Study ARQ-151-101, the percent change from baseline in the primary endpoint (TPSS x TPA) was statistically significantly different (ARQ-151 0.15%: p<0.01; ARQ-151 0.5%: p<0.01) from vehicle for both active doses of ARQ-151 after 2 weeks of treatment and the product of plaque area and severity was reduced by >65% from baseline for both active dose groups after 4 weeks of treatment.

Safety

The incidence of TEAEs was comparable to vehicle for both doses (40.0% of subjects treated with 0.5% ARQ 151 vs. 25.0% of subjects treated with 0.15% ARQ-151 vs. 35.5% of subjects treated with vehicle), and all TEAEs were predominantly mild or moderate in severity. There were no SAEs and no discontinuations due to TEAEs. There was also none of the application site adverse reactions that are commonly associated with many other topical psoriasis treatments, and no evidence of the gastrointestinal side effects commonly seen with oral administration of roflumilast or other oral PDE4 inhibitors.

While there were no adverse side effects or tolerability issues with ARQ-151 identified during study ARQ-151-101, systemic exposure seen in the study was higher than predicted by our pre-clinical pharmacokinetic experiments. We therefore elected to reduce the maximum concentration from 0.5% roflumilast to 0.3% roflumilast for subsequent development.

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Ongoing and Upcoming Trials

ARQ-151-202 Study

Subjects who completed 12 weeks of double-blind treatment in the ARQ-151-201 study were eligible to roll over to an open label long-term safety study, which is ongoing. In this study, all subjects are receiving 0.3% ARQ-151 topical cream once daily for 52 weeks. 231 subjects from Study ARQ-151-201 elected to roll over to the ARQ-151-202 study. In addition, 102 new subjects, who had not participated in the ARQ-151-201 study, were enrolled in Study ARQ-151-202. The primary endpoints of this study are the occurrence of TEAEs and the occurrence of SAEs. Study ARQ-151-202 is fully enrolled and ongoing, with topline results expected in the first half of 2021. We believe this study will fulfill regulatory submission requirements for 12 month safety data.

Phase 3 Trial Design: ARQ-151-301 (DERMIS-1) Study and ARQ-151-302 (DERMIS-2) Study

Based on the strength of the results from our Phase 2a and Phase 2b trials in plaque psoriasis, we plan to conduct a Phase 3 clinical program for ARQ-151 consisting of three trials, including two identical multi-national, multi-center, double-blind, vehicle-controlled Phase 3 clinical trials (ARQ-151-301 and ARQ-151-302) to support registration with the FDA. In these studies, which we refer to as the "Trial of P***DE***4 inhibition with ***R***oflumilast for the ***M***anagement of Plaque Psoria***is***" (DERMIS-1, DERMIS-2), we plan to enroll a total of 800 mild-to-severe plaque psoriasis patients (400 patients per study) for 8 weeks of once daily treatment with ARQ-151 0.3% cream or matching vehicle to demonstrate the superiority of ARQ-151 treatment compared to vehicle. Randomization will be in a 2:1 ratio of active drug to vehicle.

We expect that these two trials will randomize patients ages 12 and above with plaque psoriasis covering between 2% and 20% BSA. The primary efficacy endpoint will be the percentage of subjects attaining IGA Success at week 8, defined as a score of "clear" or "almost clear" PLUS a two-point improvement from baseline on the IGA scale at week 8. Multiple secondary endpoints will also be evaluated, including PASI-75, PASI-90, I-IGA in subjects with intertriginous plaques, WI-NRS in subjects with pruritus, and PSD. At the end of the 8-week treatment period, a proportion of patients will be eligible to roll over into the ARQ-151-306 (DERMIS-OLE) study.

Based on our positive October 2019 End-of-Phase 2 meeting with the FDA, we believe the design of the DERMIS-1 and DERMIS-2 studies will support the NDA submission of ARQ-151 for plaque psoriasis. We believe that if the results from DERMIS-1 and DERMIS-2 are positive, we will have sufficient efficacy data for the registration with the FDA of ARQ-151 for the treatment of plaque psoriasis, including psoriasis in intertriginous regions. We intend to use the results from DERMIS-1 and DERMIS-2, supported by the chronic treatment results from the ARQ-151-202 and ARQ-151-306 studies to support recommendations for long-term use. Safety data from Study ARQ-151-202, supplemented with data from Studies ARQ-151-101, ARQ-151-201, ARQ-154-204, ARQ-151-301, ARQ-151-302, and ARQ-151-306, will form the basis for our Integrated Safety Summary that will be required by the FDA at the time of submission. Because we are collecting 12-month exposure data from Study ARQ-151-202, we do not believe we will need any additional long-term safety studies in Phase 3.

ARQ-151-306 (DERMIS-OLE) Study

A portion of subjects who complete 8 weeks of double-blind treatment in the DERMIS-1 and DERMIS-2 studies will be eligible to roll over to an open label extension study, DERMIS-OLE. In this study, all subjects will receive 0.3% ARQ-151 topical cream for 24 weeks. Up to 250 subjects from DERMIS-1 and DERMIS-2 will be eligible to enroll in DERMIS-OLE. The primary endpoints of this study will be the occurrence of TEAEs and the occurrence of SAEs.

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Atopic Dermatitis

Completed Trials

ARQ-151-102 (Phase 1 Study)

The ARQ-151-102 was a single-site, open label Phase 1 study of the pharmacokinetics and safety of ARQ-151 in atopic dermatitis, in which 16 adults with mild to moderate atopic dermatitis covering between 4% and 8% BSA were treated for 15 days with: (1) 0.15% ARQ-151 topical cream, or (2) 0.05% ARQ-151 topical cream once daily. The primary focus of the study was to evaluate pharmacokinetics, safety and tolerability. Change from baseline in area of atopic dermatitis lesions was also measured. The study found that systemic exposure upon topical application of ARQ-151 at the same concentration and over the same BSA was similar in atopic dermatitis subjects and in psoriasis subjects. This suggests that the side effect profile and tolerability of ARQ-151 in atopic dermatitis may be similar to that seen in psoriasis. This is an important finding, as the damaged skin barrier in atopic dermatitis patients may lead to increased systemic drug exposure with some therapies. In study ARQ 151-202, ARQ-151 was well-tolerated by the subject population, with no SAEs or discontinuations due to AEs during the study, and no evidence of irritation in any subject. The mean percent BSA involvement decreased from 6.1% in the 0.15% group and 5.8% in the 0.05% group at baseline to 3.1% and 2.6%, respectively, at Week 2, reflecting reductions of 49% and 55%. While there was no vehicle control in this study, we believe these results suggest that ARQ-151 may provide symptomatic improvement in the treatment of atopic dermatitis.

Ongoing and Upcoming Trials

ARQ-151-212 Study

The ARQ-151-212 study is a multi-center, multi-national, double-blind, vehicle-controlled Phase 2a study, in which 136 adolescents (ages 12 and above) and adults with atopic dermatitis covering between 1.5% and 35% BSA were randomized to receive 4 weeks of: (1) 0.15% ARQ-151 topical cream once daily, (2) 0.05% ARQ-151 topical cream once daily, or (3) matching vehicle once daily. The primary efficacy endpoint is the change from baseline in Eczema Area and Severity Index, or EASI, Total Score at week 4. Multiple secondary outcome measures will also be assessed, including, among others, percent change from baseline in EASI Total Score, achievement of a 50% or greater improvement in EASI (EASI50) score from baseline, and Worst Itch-Numerical Rating Scale (WI-NRS) pruritus score. Enrollment was completed on October 4, 2019 and we expect to report topline results from this study by the end of 2019. If the topline results from Study ARQ-151-212 are positive, we intend to initiate a Phase 2b study in atopic dermatitis in the second half of 2020 with topline results in the second half of 2021.

ARQ-154

Overview

We are also developing ARQ-154, a foam formulation of ARQ-151 for the treatment of scalp psoriasis and seborrheic dermatitis. ARQ-154 contains roflumilast, the same highly potent and selective PDE4 inhibitor found in ARQ-151, and is nearly identical to ARQ-151, with all ingredients in ARQ-154 being the same as those in ARQ-151, other than reduced oil content and the addition of a propellant in the can to create the foam. We plan to initiate Phase 2b studies for ARQ-154 in both seborrheic dermatitis and scalp psoriasis in Q4 2019/Q1 2020.

Product Profile and Differentiation

ARQ-154 is a light foam, similar to hair mousse, that has been designed to deliver the drug to the scalp while not leaving a greasy residue or disturbing hair style. The foam breaks easily upon agitation,

creating a thin solution that can be rubbed easily into the scalp. Additionally, the product does not melt on the fingers prior to application. ARQ-154 will not stain clothing or bedding, and does not have an unpleasant smell. ARQ-154 is designed for simple once-a-day application and neither burns nor stings on application. We believe that ARQ-154 has the potential to offer physicians and patients a highly differentiated clinical profile that is ideally suited to address unmet needs in the topical treatment of scalp psoriasis and seborrheic dermatitis.

Seborrheic Dermatitis

Seborrheic Dermatitis Background

Seborrheic dermatitis is a common skin disease that is estimated to occur in approximately 2% of the population. The disease causes red patches covered with large, greasy, flaking yellow-gray scales, and is frequently itchy. It appears most often on the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back as depicted in the figure below. A milder variant of the disease is dandruff. While the pathogenesis of seborrheic dermatitis is not well understood, some experts believe a contributor is an over-abundance of *Malassezia*, a naturally occurring yeast found on normal skin but found in excess numbers on skin with seborrheic dermatitis. There also is an immunological or inflammatory component, possibly as a result of the proliferation of the *Malassezia* yeast and its elaboration of substances that irritate the skin. Seborrheic dermatitis can occur in both adults and infants, and in infants is commonly referred to as “cradle cap”.

Figures: Seborrheic Dermatitis

Current Seborrheic Dermatitis Treatment Landscape

There are a number of widely used treatments for seborrheic dermatitis, including antifungal agents, lower potency steroids, and immunomodulators.

- **Antifungal agents**, particularly azoles such as ketoconazole, are the cornerstone of therapy for seborrheic dermatitis. These agents are available in a variety of formulations suitable for treating areas of the body affected by seborrheic dermatitis, including shampoos, foams, gels, and creams. Oral antifungals are occasionally used in very severe cases. Antifungals in the treatment of seborrheic dermatitis are generally well tolerated, although some patients experience irritant contact dermatitis, a burning or itching sensation, or dryness.
- **Topical steroids**, mostly low- to mid-potency, are often prescribed for patients suffering from seborrheic dermatitis because of the inflammatory component of the disease. Due to the risks associated with steroid use, particularly on the face, such as skin atrophy (thinning), telangiectasias (spider veins), folliculitis (inflammation of the hair follicle), and hypertrichosis

(abnormal hair growth), physicians try to limit duration or avoid steroid therapy. The eyebrows and nasolabial folds are the most common sites of seborrheic dermatitis on the face. Their proximity to the eyes and the known association of steroid use with the development of cataracts and glaucoma add to physicians' apprehension in prescribing topical steroids for seborrheic dermatitis.

- **TCIs** are also used off-label for the treatment of seborrheic dermatitis. These agents appear to provide symptomatic improvement in seborrheic dermatitis due to their anti-inflammatory effects. Many doctors are more comfortable using these drugs compared to steroids, especially on the face and around the eyes. As previously noted, TCIs carry a boxed warning for the potential increased risk of cancers, especially lymphomas, associated with their use, and physicians generally try to avoid long-term use in patients suffering from seborrheic dermatitis. Additionally, because TCIs are >800 Da in molecular weight, and since seborrheic dermatitis does not have a skin permeability defect, TCIs only provide symptomatic improvement in seborrheic dermatitis in areas of skin that are very thin and where the drug can penetrate (i.e., largely the periocular areas only).

While physicians have a number of relatively inexpensive treatment options that provide symptomatic improvement for seborrheic dermatitis, the greatest unmet need relates to inadequate response to existing therapies in some patients, particularly in patients with more severe disease. Physicians report that up to one-third of severe patients suffering from seborrheic dermatitis, and a smaller percentage of mild- and moderate-severity patients, have an inadequate response to current seborrheic dermatitis treatments. This treatment resistant population represents a key opportunity for ARQ-154. Additionally, physicians are wary of using steroids on the face due the risk of skin thinning, spider veins, folliculitis, and unnatural hair growth. Physicians are especially wary of using steroids near the eyes due to the potential increased risk of cataracts and glaucoma. Finally, many physicians are reluctant to treat chronically with steroids and TCIs, the main anti-inflammatory agents used in treatment of seborrheic dermatitis. Therefore, in addition to the opportunity in treatment resistant patients, we believe ARQ-154 may be an option for some patients as a first-line therapy, especially patients with involvement of the face.

We believe physicians are seeking new therapies for seborrheic dermatitis that provide more symptomatic improvement than the current treatment paradigm, especially in those patients with an inadequate response to existing therapies. Furthermore, we believe an unmet need exists for an agent that not only provides the ability to be used chronically with a low risk of side effects, but also the ability to use on the face and near the eyes with a low risk of ocular side effects. Given most patients suffering from seborrheic dermatitis have scalp involvement, we believe a formulation suitable for treating hair-bearing areas of the scalp is essential.

Scalp Psoriasis

Scalp Psoriasis Background

Scalp psoriasis is a manifestation of plaque psoriasis that occurs in nearly half of all psoriasis patients, characterized by plaques in the hair-bearing area of the scalp and sometimes extending to the forehead, back of the neck, or behind or inside the ears as depicted in the figure below. These psoriatic plaques are identical to plaques on other body areas, however topical treatment of these plaques is complicated by the difficulty of delivering topical drugs under hair-bearing areas. As with psoriatic plaques on other parts of the body, psoriasis on the scalp is often itchy and is sometimes painful. Scalp psoriasis can also be associated with hair loss, likely due to damage to the hair from excessive scratching, rubbing, or combing of the affected area.

Figures: Scalp Psoriasis
Source (left): DermNet

Current Scalp Psoriasis Treatment Landscape

Scalp psoriasis treatments are similar to plaque psoriasis given the plaques are identical to the plaques in other body areas. Both biologics and systemic treatments will improve scalp psoriasis but suffer from the same limitations as in plaque psoriasis. Additionally, there is no evidence that adoption is greater in scalp psoriasis patients than other psoriasis patients.

High-potency steroids and vitamin D3 analogs, topical agents that provide symptomatic improvement in plaque psoriasis, also provide symptomatic improvement in scalp psoriasis. However, due to the hair on most scalp psoriasis patients' scalps, lotions, creams and ointments are not appropriate for use on the scalp because of the difficulty of delivering the drug to the scalp. The negative impact on hair appearance can also affect patient compliance. A number of alternative formulations have been developed, such as solutions, suspensions, foams, or shampoos, containing high-potency steroids, vitamin D3 analogs, or a combination of the above. However, these formulations are also not ideal as the solutions and suspensions often run down patients' faces or into their ears, and some foam formulations are too greasy upon application. Other foam formulations melt upon application to the fingers before they can be applied to the scalp. More importantly, these formulations have the same risk of side effects and tolerability issues as their cream, ointment, and lotion counterparts. Physicians are especially concerned about the use of steroids to treat scalp psoriasis due to the potential for steroid exposure in the eye, and the resulting increased risk of cataracts and glaucoma.

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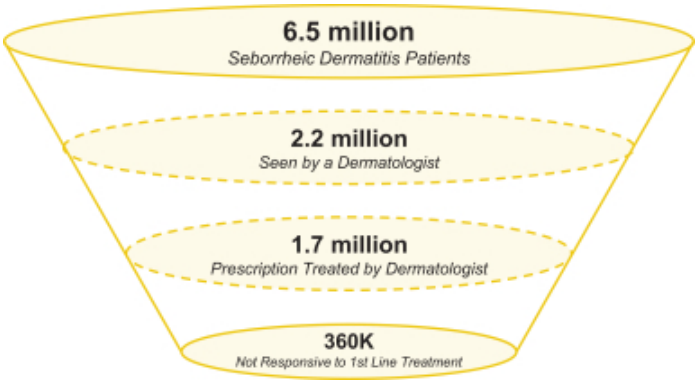
We believe physicians are seeking a novel topical treatment for scalp psoriasis with the same characteristics as an ideal plaque psoriasis treatment (namely rapid onset, symptomatic improvement of a high-potency steroid, ability to use chronically with a low risk of side effects, no risk of rebound or tachyphylaxis, and ability to use in the periocular area with a low risk of side effects), but in a formulation that is convenient to use on hair-bearing areas of the scalp.

Our Market Opportunity

Seborrheic Dermatitis

We believe there is a significant market opportunity for us to capture within seborrheic dermatitis. As depicted below, we estimate there are approximately 6.5 million patients in the United States with seborrheic dermatitis, of which 2.2 million patients are treated by a dermatologist. Approximately 1.7 million patients receive prescription treatment for their seborrheic dermatitis from a dermatologist, and about 360,000 of those patients have an inadequate response to existing treatments, and thus would be the most likely candidates for a product like ARQ-154. We believe ARQ-154 may also be a first-line option for some of the other approximately 1.3 million patients treated by a dermatologist, especially due to concerns with steroid use in patients with involvement of the face. There is an even larger opportunity in the primary care setting that we intend to pursue through commercial partnerships.



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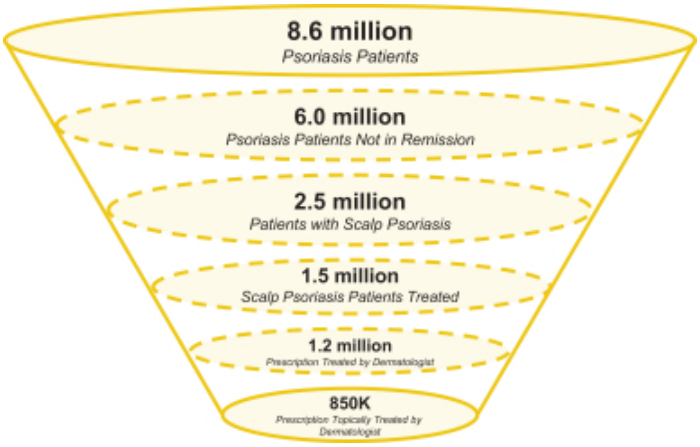
Scalp Psoriasis

We believe there is a significant market opportunity for us to capture within scalp psoriasis. As depicted below, we estimate that of the 8.6 million psoriasis patients in the United States, approximately 2.5 million patients have active disease with involvement of the scalp. Of the population with scalp psoriasis, approximately 1.5 million patients are treated, with approximately 82% treated by dermatologists, and some 850,000 patients are treated with topical prescriptions from dermatologists.



ARQ-154 Clinical Development

We are planning to initiate two Phase 2b studies with ARQ-154, one in scalp psoriasis and another in seborrheic dermatitis, in Q4 2019/Q1 2020.

Clinical Development Plan

ARQ-154-203 (Phase 2b Study)

Study ARQ-154-203 is a multi-center, multi-national, double-blind, vehicle-controlled Phase 2b study, in which approximately 150 adolescents (ages 12 and above) and adults with seborrheic dermatitis covering up to 20% BSA will be randomized to receive 8 weeks of (1) 0.3% ARQ-154 topical foam once daily, or (2) matching vehicle once daily. Randomization will be 2:1, active to vehicle. The primary efficacy endpoint will be the percentage of patients an IGA score of “clear” or “almost clear” PLUS a 2-grade improvement from baseline at week 8. We expect that the ARQ-154-203 study will begin enrollment Q4 2019/Q1 2020 and we expect results from this study by the second half of 2020. If the results from the ARQ-154-203 study are positive, we expect to continue the development of ARQ-154 for the topical treatment of seborrheic dermatitis.

ARQ-154-204 (Phase 2b Study)

Study ARQ-154-204 is a multi-center, multi-national, double-blind, vehicle-controlled Phase 2b study, in which approximately 300 adolescents (ages 12 and above) and adults with scalp psoriasis covering at least 10% of the total scalp and total psoriasis involvement in all body areas of up to 20% BSA will be randomized to receive 12 weeks of (1) 0.3% ARQ-154 topical foam once daily, or (2) matching vehicle once daily. Randomization will be 2:1, active to vehicle. The primary efficacy endpoint will be the percentage of patients achieving a Scalp-IGA score of “clear” or “almost clear” PLUS a 2-grade improvement from baseline at week 8. We expect that the ARQ-154-204 study will begin enrollment Q4 2019/Q1 2020, and we expect to report topline results from this study Q4 2020/Q1 2021. If the results from the ARQ-154-204 study are positive, we expect to continue the development of ARQ-154 for the topical treatment of scalp psoriasis.

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ARQ-252

Overview

ARQ-252 is our small molecule inhibitor of JAK1 that we are developing for hand eczema and vitiligo. We plan to initiate a Phase 2b study of ARQ-252 in adult patients with hand eczema in the first half of 2020, with topline data expected in second half of 2021. We also plan to initiate a Phase 2a study of ARQ-252 in vitiligo in the second half of 2020.

In January 2018, we signed the Hengrui License Agreement for an option to an exclusive license to the active pharmaceutical ingredient in ARQ-252 for all topical dermatological uses in the United States, Europe and Japan. Hengrui is developing SHR-0302, the active ingredient in ARQ-252, for the oral treatment of various inflammatory and immunological disorders, including rheumatoid arthritis, Crohn's disease, and ulcerative colitis, and have completed a Phase 2b study in rheumatoid arthritis. Under our agreement, we have the right to reference their safety data, along with the systemic toxicology data supporting their program. Hengrui has built strong intellectual property protection around the active ingredient in ARQ-252, and holds U.S. composition of matter patents, including patents that extend into 2034 for the bisulfate form of the active ingredient. We believe there is the potential for additional intellectual property protection of ARQ-252 through possible future formulation and other patents.

Mechanism of Action

JAK1 is one of the janus family of non-receptor protein tyrosine kinases (JAKs), including JAK1, JAK2, and JAK3, and tyrosine kinase type 2, or Tyk2. Collectively, these kinases are involved in cell growth, survival, development, and differentiation of a variety of cells; specifically, JAK1, JAK3, and Tyk2 are critically important for immune cells and JAK2 is critically important for hematopoietic cells. JAK1, JAK3 and Tyk2 all play key roles in regulation of immune function and inflammation, and genetic mutations of these three kinases result in severe clinical immunodeficiencies such as severe combined immune-deficiency syndrome and autosomal recessive hyperimmuno-globulin E syndrome. Inhibitors of JAK1 and/or JAK3, and more recently Tyk2, have been shown to provide symptomatic improvement for a wide range of immunologically-driven diseases, including rheumatoid arthritis, psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis, alopecia areata, and atopic dermatitis.

A wide range of receptors involved in hematopoietic cell development, including erythropoietin, thrombopoietin, and granulocyte-macrophage colony-stimulating factor, or GM-CSF, rely on JAK2 signaling. Unsurprisingly, genetic mutations of JAK2 result in myeloproliferative disorders, and JAK2 inhibition has been shown to provide symptomatic improvement as a therapeutic option for myelofibrosis, which often involves overexpression of JAK2, and other hematological diseases.

Topical JAK inhibitors have been shown to provide significant symptomatic improvement in the treatment of atopic dermatitis and eczema, and more recently, in vitiligo, although they are much less effective in psoriasis. The principal challenge with JAK treatment is the safety profile of JAK inhibitors. Inhibition of JAK2 may lead to neutropenia, thrombocytopenia, anemia, or increased thromboembolism. Inhibition of JAK1 may lead to serious or opportunistic infections, tuberculosis, or lymphoma and other malignancies. Topical administration may reduce these risks substantially compared to oral administration of JAK inhibitors due to the reduced systemic exposure through topical administration.

Product Profile and Differentiation

ARQ-252 is topical cream formulation of a potent and highly selective topical, small molecule inhibitor of JAK1. As seen in the table below, ARQ-252 has been observed in a preclinical study

conducted by us to be highly selective to JAK1 over JAK2, in stark contrast to ruxolitinib, the furthest advanced topical JAK inhibitor in development for atopic dermatitis and vitiligo. In the table below, a lower IC50 value, a common measurement of drug potency, indicates a lesser amount is required to inhibit the various JAK subtypes. The ARQ-252 JAK1:JAK2 IC50 ratio is 23.5:1, compared to ruxolitnib's JAK1:JAK2 IC50 ratio of 2.6:1. We believe that due to its high selectivity for JAK1 over JAK2, ARQ-252 has the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition.

JAK Inhibitor Potency in Cell-based Assay System

	JAK1/3 Inhibition						JAK2 Inhibition
	IL-2		IL-4		IL-6		
IC50 (μM)	CD-4	CD-8	CD-4	CD-8	CD-4	CD-8	GM-CSF
ARQ-252	1.15	1.05	2.29	1.39	5.22	1.66	50*
Ruxolitinib	1.48	1.25	3.24	1.87	4.49	1.50	6.08

* A value of 50 μM was used as the IC50 value for the purpose of assigning a ratio, since 50% inhibition of JAK2 was not reached. The average percentage inhibition measured in the GM-CSF assay was 23.5% at 20 μM. While 50 μM was used, we believe that the IC50 value is greater than 50 μM, but likely < 100 μM.

Additionally, in mid-2019, Hengrui completed a Phase 2b study in rheumatoid arthritis that used the same active pharmaceutical ingredient as in ARQ-252 but dosed orally. The results from this study confirmed that this active pharmaceutical ingredient is a highly potent inhibitor of JAK1 based on the drug's impact on rheumatoid arthritis, and it was generally well tolerated at exposures well above those expected with topical administration of ARQ-252.

We believe that ARQ-252 could offer a best-in-class topical JAK inhibitor, with a more favorable tolerability profile than other topical JAK inhibitors due to its selectivity to JAK1 over JAK2, robust symptomatic improvement due to its high-potency against JAK1, and a convenient and patient-friendly cream formulation.

Hand Eczema

Hand Eczema Background

Eczema is a term used to describe a group of different diseases that cause the skin to become red, itchy and inflamed. There are multiple forms of eczema, including atopic dermatitis, contact dermatitis, hand eczema, dyshidrotic eczema, and seborrheic dermatitis. Eczema is very common, with some estimates that up to 30 million people in the United States may have some form of eczema.

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Hand eczema is a common, predominantly inflammatory, skin disease. It is the most common skin disease affecting the hands, with prevalence estimated at up to 2.5% of the population. Hand eczema is characterized variously by redness, fluid filled blisters or bumps, scaling, cracking, itching and pain occurring on the hands, especially the palms (see figures below). It is a diverse syndrome, incorporating dyshidrotic eczema, an immune disease possibly related to atopic dermatitis; irritant contact dermatitis of the hands, which is caused by occupational irritants such as chemicals; allergic contact dermatitis of the hands, which is caused by an allergic reaction; atopic hand dermatitis, which is atopic dermatitis occurring on the hands, and hyperkeratotic hand dermatitis, which are thickened, scaly, red plaques, similar to psoriasis, on the hands. The impact of hand eczema on patients can be significant, leading to work absences or disability, social stigmatization, and psychosocial distress.

Figures: Hand Eczema

Current Hand Eczema Treatment Landscape

Hand eczema is a difficult disease to treat, particularly because it is more difficult to deliver drugs topically on the palms of the hand due to the thicker skin, which can be up to ten times thicker than skin from other body areas, which inhibits drug absorption. Hand eczema is typically treated with high-potency topical steroids, mostly due to the aforementioned skin barrier challenges. In some cases, physicians also will incorporate barrier creams to aid in hydration and to prevent the irritant effect caused by occupational exposure, a common cause of hand eczema. There are currently no FDA-approved treatments specifically for the indication of hand eczema.

Physicians report that a significant percentage of patients, including up to 40% of patients with severe dyshidrotic eczema (one type of hand eczema), have an inadequate response to currently available treatments. In those who respond to high-potency topical steroids, skin atrophy becomes a problem with chronic use, even on the thick skin of the palms. Because hand eczema is painful and can be debilitating, there is a high sense of urgency to treat effectively. Physicians and patients would like a new therapy that provides symptomatic improvement with a low risk of side effects and favorable tolerability profile.

Other Indications

Vitiligo

Vitiligo is a disfiguring disease that causes the complete loss of skin color in blotches or patches in a symmetrical distribution. The disease is caused by the localized complete destruction by the immune system of melanocytes, the skin cells that produce skin pigmenting melanin, resulting in

complete depigmentation in the affected area. We plan to initiate a Phase 2a clinical trial in the second half of 2020. Ruxolitinib, another topical JAK inhibitor, has shown some promising results in the treatment of vitiligo, although there are clearly opportunities to improve on the profile shown with that other agent thus far.

ARQ-252 Clinical Development

We are planning to initiate two clinical studies with ARQ-252 in 2020, one in hand eczema and one in vitiligo.

ARQ-252-205 Study (Phase 2b Study)

We plan to initiate our first study with ARQ-252, the ARQ-252-205 Study, in the first half of 2020. This study will be a multi-center, multi-national, double-blind, randomized, vehicle-controlled Phase 2b study, in which 245 adults with chronic hand eczema will be randomized to receive: (1) 0.1% ARQ-252 cream applied once daily, or (2) 0.3% ARQ-252 cream applied once daily, or (3) 0.3% ARQ-252 cream applied twice daily, or (4) matching vehicle cream applied once or twice daily, all for 12 weeks. The primary efficacy endpoint will be an IGA of “clear” or “almost clear” PLUS at least a 2-point improvement from baseline at week 12.

ARQ-252-213 Study (Phase 2a Study)

We are currently developing the protocol for a Phase 2a study, ARQ-252-213, to evaluate ARQ-252 for the topical treatment of vitiligo. JAK1 as a target for vitiligo has been validated by Incyte’s recent results on topical ruxolitinib. Given the results of the ruxolitinib vitiligo study, this study will likely concentrate on vitiligo of the face, which causes psychosocial problems for the afflicted person, and is also generally the anatomic area of disease most responsive to treatment because of the proximity of hair follicles which help in the repigmentation process. This study will be a multi-center, multi-national, double-blind, randomized, vehicle controlled Phase 2a study in adults with vitiligo. The primary efficacy endpoint will be percent improvement from baseline in the Face Vitiligo Area Scoring Index (F-VASI) score. We plan to start this study in the second half of 2020. If the results of the ARQ-252-213 study are positive, we plan to continue the development of ARQ-252 for the topical treatment of vitiligo.

ARQ-255

Overview

We are also developing ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. Alopecia areata is an autoimmune disorder that causes the immune system to incorrectly attack the body’s own cells, specifically the hair follicles, leading to loss of hair—usually in patches—on the scalp, face or sometimes other areas of the body. While oral JAK inhibitors have shown symptomatic improvement in the treatment of alopecia areata, multiple topically applied JAK inhibitors have failed to demonstrate symptomatic improvement in alopecia areata. It is our belief that this discrepancy is due to the site of inflammation driving alopecia areata, deep in the skin at the base (bulb) of the hair follicle. While oral JAK inhibitor administration can achieve required levels of drug at the site of inflammation, conventional topical applications are unlikely to deliver concentrations of JAK inhibitors to the site of inflammation adequate to treat alopecia areata. We have undertaken a formulation effort we refer to as Deep Dermal Drug Delivery (“4D” technology), that leverages some of the unique physical properties of the active pharmaceutical ingredient in ARQ-255, and which we believe may allow us to topically deliver sufficient concentrations of the drug to potentially treat alopecia areata via topical administration. Formulation and preclinical experiments are underway to develop a 4D version of ARQ-252, which we refer to as ARQ-255, and if those formulation efforts are successful, we plan to enter the clinic with ARQ-255 as a potential treatment for alopecia areata.

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Competition

The biotechnology and pharmaceutical industry is highly competitive, and is characterized by rapid and significant changes, intense competition and a bias towards proprietary products. We will face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, and generic drug companies. Any product candidate that we successfully develop and commercialize will compete with existing treatments, including those that may have achieved broad market acceptance, and any new treatment that may become available in the future.

Many of our competitors have greater financial, technical and human resources than we have. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that offer more symptomatic improvement, have a lower risk of side effects or are less costly than our current or future product candidates.

Our success will be based in part on our ability to identify, develop and commercialize a portfolio of product candidates that have a lower risk of side effects and/or provide more symptomatic improvement than competing products.

For psoriasis, our primary competitors include injected biologic therapies such as Humira, marketed by AbbVie Inc. and Eisai Co., Ltd., and Enbrel, marketed by Amgen Inc., Pfizer Inc., and Takeda Pharmaceutical Company Limited; non-injectable systemic therapies used to treat plaque psoriasis such as Otezla, marketed by Celgene Corporation; topical therapies such as branded and generic versions of clobetasol, such as Clobex, marketed by Galderma Laboratories, LP; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat psoriasis and compete with ARQ-151, including tapinarof, under development by Dermavant Sciences, Inc., and SNA-120, under development by Sienna Biosciences, Inc.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., and generic and branded versions of low to mid-potency steroids such as hydrocortisone and betamethasone; and the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with ARQ-151, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc., oral PF-04965842, under development by Pfizer Inc., oral upatacitinib, under development by AbbVie, Inc. and injectable lebrikizumab, under development by Dermira, Inc.

For hand eczema, our primary competitors include topical therapies such as branded and generic versions of clobetasol, such as Clobex, and generic versions of betamethasone dipropionate. The only other prescription product candidate we are aware of under development for the treatment of hand eczema that would compete with ARQ-252 is delgocitinib.

For vitiligo, our primary competitors include topical therapies such as generic and branded versions of calcineurin inhibitors, including Elidel, marketed by Bausch Health; branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat vitiligo and

compete with ARQ-252, including but not limited to: topical cerdulatinib, under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, and both PF-06651600 and PF06700841, under development by Pfizer Inc.

For alopecia areata, our primary competitors include topical therapies such as branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; intralesional corticosteroid injections such as branded and generic versions of triamcinolone, including Kenalog, marketed by Bristol-Myers Squib; and systemic immunosuppressants including generic versions of systemic steroids such as prednisone, branded and generic versions of cyclosporine, including Sandimmune, marketed by Sandoz, and branded systemic JAK inhibitors, including Xeljanz, marketed by Pfizer, Inc.. In addition, there are several prescription product candidates under development that could potentially be used to treat alopecia areata and compete with ARQ-255, including but not limited to: PF-06651600, under development by Pfizer, Inc., CTP-543, under development by Concert Pharmaceuticals, and baricitinib, under development by Eli Lilly and Company.

Commercial Operations

We intend to build our own commercial infrastructure in the United States and Canada to support the commercialization of our product candidates. We intend to begin building this commercial infrastructure if and when we believe that a regulatory approval of our first product candidate appears reasonably likely. We plan to build our own small specialty sales force targeted at dermatologists. We do not intend to target pediatricians or primary care physicians, but plan to seek partnerships that allow us to target these specialties if required to maximize the potential of our product candidates. We also plan to build the required sales management, marketing, access and reimbursement, sales support, and distribution capabilities to optimize our commercial success. To develop the required commercial infrastructure, we will have to invest substantial financial and management resources, some of which will be committed prior to any confirmation that our product candidates will be approved, and we could invest resources and then later learn that a particular product candidate is not being approved. We may also seek other partners to help us access other geographic markets.

Intellectual Property

Maintaining proprietary rights in our product candidates and technologies will assist in achieving the success of our business. One way in which we obtain and maintain such proprietary rights is by filing patent applications and maintaining patents covering our core technologies and product candidates. Our policy is to file such patent applications in the United States and select foreign countries to better protect our worldwide interests. We also seek to avoid infringing the proprietary rights of others. For this reason, we routinely monitor and evaluate third-party patents and publications, and, if necessary, take appropriate action based on that evaluation.

Patent term is based on the filing or grant date of the patent, as well as the governing law of the country in which the patent is obtained. In the United States, some pharmaceutical patents are also eligible for Patent Term Extension, or PTE, which can extend exclusivity for up to 5 additional years under certain conditions. The protection provided by a patent varies from country to country, and is dependent on the type of patent granted, the scope of the patent claims, and the legal remedies available in a given country.

As of September 30, 2019, we own or have an exclusive option to exclusively license to nine issued U.S. patents and six issued foreign patents, which include granted European patent rights that have been validated in various EU member states, and six pending U.S. patent applications, 9 pending

foreign patent applications and three applications filed under the Patent Corporation Treaty. Of these patents and patent applications:

- **ARQ-151 & ARQ-154**: As of September 30, 2019, we own five issued U.S. patents, one issued Canadian patent, one issued Japanese patent, four pending U.S. patent applications and six pending foreign applications (one each in China, Hong Kong, Japan, and three under the Patent Cooperation Treaty), relating to ARQ-151 and ARQ-154. The issued U.S. patent that we have licensed from AstraZeneca claiming composition of matter of roflumilast, the active pharmaceutical ingredient in ARQ-151 and ARQ-154 is set to expire on January 27, 2020. Our issued patents relating to ARQ-151 and ARQ-154 contain claims directed to, among other things, formulating roflumilast in combination with hexylene glycol, methods of making such formulations and methods of treatment using such formulations. These issued U.S. patents relating to ARQ-151 and ARQ-154 will expire not earlier than June 2037 (excluding any potential PTE).
- **ARQ-252 & ARQ-255**: As of September 30, 2019, we have an exclusive option to exclusively license from Hengrui four issued U.S. patents, two issued Japanese patents, and two issued EU patents (validated in a number of EU member states, including Austria, Belgium, Bulgaria, Croatia, the Czech Republic, Estonia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxemburg, Monaco, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovenia, Slovakia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom), two pending U.S. patent applications, three pending Japanese patent applications, and three pending EU patent applications relating to SHR0302. These patents and patent applications contain claims directed towards the composition of matter of the SHR0302 compound and bisulfate and crystalline forms thereof, pharmaceutical compositions and treatment methods. The issued patents and pending applications, if issued, relating to SHR0302 will not expire earlier than 2033. We anticipate filing patent applications directed towards formulations, methods and other aspects of our technology relating to ARQ-252 and ARQ-255 which we may develop in the future.

Obtaining patent protection is not the only method that we employ to protect our propriety rights. We also utilize other forms of intellectual property protection, including trademark, and trade secrets, when those other forms are better suited to protect a particular aspect of our intellectual property. Our belief is that our propriety rights are strengthened by our comprehensive approach to intellectual property protection.

Maintaining the confidential nature of our non-publicly disclosed products and technologies is of paramount importance. For this reason, our employees, contractors, consultants and advisors are required to enter into nondisclosure and invention assignment agreements when their employment or engagement commences. Those individuals also enter into agreements that prohibit the communication or implementation of any third-party proprietary rights during the course of their employment with us. We also require any third-party that may receive our confidential information or materials to enter into confidentiality agreements prior to receipt of that information or material.

Exclusive License and Option Agreements

AstraZeneca AB

In July 2018, we entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca AB, or AstraZeneca, pursuant to which we obtained a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, commercialize and otherwise exploit products containing roflumilast in topical forms, as well as delivery

systems sold with or for the administration of roflumilast, or collectively, the AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. We intend to develop topical formulations of roflumilast for the treatment of psoriasis and atopic dermatitis, as well as other dermatological conditions. Under this agreement, we have sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at our expense, and we shall use commercially reasonable efforts to develop, obtain and maintain regulatory approvals for, and commercialize the AZ-Licensed Products in the Dermatology Field in each of the United States, Italy, Spain, Germany, the United Kingdom, France, China, and Japan. Pursuant to the agreement, AstraZeneca provided us with certain quantities of roflumilast at a negotiated price for development purposes.

We paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 969,117 shares of our Series B Preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. In addition, we have agreed to make cash payments to AstraZeneca of up to an aggregate of $14.5 million upon the achievement of specified clinical development and regulatory approval milestones with respect to the AZ-Licensed Products and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. The first milestone cash payment of $2.0 million was earned upon the achievement of positive Phase 2 data for any AZ-Licensed Product, and we paid this in August 2019 upon the completion of a Phase 2b study of ARQ-151 in plaque psoriasis. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on a AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country.

The agreement continues in effect until the expiration of all royalty obligations as described above, unless earlier terminated: (1) by either party upon written notice for the other party's material breach or insolvency event if such party fails to cure such breach or the insolvency event is not dismissed within specified time periods; (2) by AstraZeneca if we, our affiliates, or our sublicensees take actions to invalidate AstraZeneca-licensed patent rights, or if we permanently cease development of all AZ-Licensed Products, and an AZ-Licensed Product is not being commercialized by us; or (3) by us upon 120 days' written notice or in the event of certain adverse clinical trial or other regulatory outcomes. In the event the agreement is terminated, except by us for AstraZeneca's material breach or in the event of certain adverse clinical trial or other regulatory outcomes, we will be obligated to pay a termination fee in the amount of $5.0 million or 3% of net sales of AZ-Licensed Products for the 3-year period following the first regulatory approval of an AZ-Licensed Product, whichever is greater.

Jiangsu Hengrui Medicine Co., Ltd

In January 2018, we entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd, or Hengrui, whereby Hengrui granted us an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions, or the Field, in the United States, Japan, and the European Union (including for clarity the United Kingdom), or the Territory. The initial option period under the Hengrui License Agreement extended to June 2019, and was subsequently amended to extend until January 2020. During the option period, in connection with evaluating whether or not to exercise our option, we have the right to develop topical formulations of SHR0302 and run certain preclinical studies and proof of concept clinical studies for SHR0302, and we must use commercially reasonable efforts to conduct a proof of concept clinical study for SHR0302 within a negotiated time

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frame. Additionally, Hengrui provides us with access to certain Hengrui know-how related to SHR0302 and limited quantities of SHR0302 (at a negotiated price) to allow us to conduct such activities during the option period.

We may exercise our exclusive option during the option period. If we exercise our option, we will have a license from Hengrui under certain patent rights and know-how controlled by Hengrui to research, develop and commercialize products containing SHR0302 in the Field in the Territory. Such license is sublicensable through multiple tiers, exclusive as to the patent rights licensed from Hengrui and non-exclusive with respect to the know-how licensed from Hengrui, and does not extend to patent rights for improvements to SHR0302 which Hengrui may come to control in the future unless otherwise mutually agreed by the parties. Upon our exercise of our exclusive option, we will have sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products in the Field and in the Territory, at our sole cost and discretion, and shall use commercially reasonable efforts to (1) develop at least one licensed product and to (2) commercialize the licensed products following regulatory approval thereof. Pursuant to the Hengrui License Agreement, a joint coordination committee reviews the progress of development and commercialization of each parties' products containing SHR0302 in their respective territories and fields.

During the option period, and during the term of the Hengrui License Agreement after we exercise our exclusive option, if we acquire or develop certain JAK inhibitor products that are not controlled by Hengrui, or Competing Products, we must negotiate in good faith with Hengrui whether to terminate the agreement or license to Hengrui the right to develop and commercialize such Competing Product in China. During the option period, and during the term of the Hengrui License Agreement after we exercise our exclusive option, Hengrui will not develop or commercialize SHR0302 or any licensed product in the Field in the Territory. Additionally, during such period if Hengrui decides to develop or commercialize a non-topical formulation of SHR0302 for the treatment of certain dermatologic indications in the Territory, we have the first right to negotiate a co-development and/or co-commercialization agreement with Hengrui for the same. We also have the right of first refusal if Hengrui decides to out-license a non-topical formulation of SHR0302 for the treatment of certain dermatologic indications in the Territory to a third party during such period.

We made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui License Agreement option and license agreement. If we exercise our exclusive option, we will pay Hengrui an additional $1.5 million option exercise cash payment. In addition, if exercised, we have agreed to make cash payments of up to an aggregate of $20.5 million upon our achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional $200.0 million in sales-based milestones based on achieving certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products we commercialize under the agreement, we will pay tiered royalties to Hengrui on net sales of each licensed product by us, or our affiliates, or our sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the later of (1) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, we are obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income we receive from sublicensees of our rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

If we exercise our exclusive option, the agreement continues in effect until the expiration of our obligation to pay royalties as described above, unless earlier terminated in accordance with the following: (1) by either party upon written notice for the other party's material breach or insolvency event if such party fails to cure such breach or the insolvency event is not dismissed within specified

time periods; and (2) by us for convenience upon 90 days prior written notice to Hengrui and having discussed and consulted any potential cause or concern with Hengrui in good faith.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other governmental authorities. The Federal Food, Drug, and Cosmetic Act, or FDC Act, and its implementing regulations, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, quality control, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending new drug applications, or NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing, and control, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP,

requirements, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to evaluate the efficacy of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of efficacy and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk profile of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances, such as where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

Assuming successful completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,940,000 for Fiscal Year 2020. The manufacturer and/or sponsor under an approved NDA is also subject to an annual program fee, currently exceeding $325,000 for each prescription drug product for 2020. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the additional information must be included in any resubmitted NDA, which is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of receipt of a standard NDA for a product that is not a new molecular entity, or NME, and six months from the date of receipt for an NDA for a non-NME subject to priority review, to review and act on the submission. In the case of an NME, the six and ten month review periods are measured from the date on which the FDA "files" the NDA rather than the date on which the NDA is received by the FDA. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP, requirements is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter, which states that the application will not be approved in present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will typically issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications, and approved product labeling may contain certain contraindications, warnings, or precautions. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, including Phase 4 clinical trials to further assess a drug's safety after approval. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Certain changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

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Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of these clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act as amended and reauthorized, certain NDAs or supplements to NDAs must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority review applications, with all of the benefits that designation confers.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA. For instance, the FDA closely regulates the post-approval labeling, marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. There also are continuing, annual program fee requirements for any marketed products.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety

information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or PDMA. In addition, the Drug Supply Chain Security Act, or DSCSA, has imposed new “track and trace” requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten-year period. The DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug “pedigree” requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA’s new national licensing standard, current state licensing requirements typically remain in effect.

The Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA’s prior findings of safety and efficacy for an existing product, or published literature, in support of its application. However, a drug must meet certain criteria relative to the Listed Drug to be eligible to use the Section 505(b)(2) pathway as opposed to the abbreviated new drug application, or ANDA pathway, which is described below. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an ANDA. An ANDA generally provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version can often be substituted by pharmacists under prescriptions written for the reference listed drug.

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Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or a Section 505(b)(2) NDA.

Upon submission of an ANDA or Section 505(b)(2) NDA, the applicant must certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The applicant may also elect to submit a statement certifying that its proposed label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the application until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant.

The application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

The Hatch-Waxman Act establishes period of regulatory exclusivity for certain approved drug products during which the FDA cannot approve (or in some cases accept for review) an ANDA or 505(b)(2) NDA that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon NDA approval of a drug containing a new chemical entity, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another applicant that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval.

Five-year and three-year exclusivity will not delay the submission or approval of a full 505(b)(1) NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of

reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The ACA amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal False Claims Act. The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offerer or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by HIPAA which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by HITECH, and their respective implementing regulations, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

Further, pursuant to the ACA, the CMS has issued a final rule that requires manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The first reports were due in 2014 and must be submitted on an annual basis. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties. Effective January 1, 2022, reporting on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives will also be required.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations,

imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any new therapeutic product candidate. Sales in the United States will depend in part on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which reimbursement for therapeutic product candidates may be sought can be subject to challenge, reduction or denial by payors.

The regulations that govern coverage, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, a drug company can obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of that product.

A drug company's ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if one or more products are successfully brought to the market, these products may not be considered cost-effective, and the amount reimbursed for such products may be insufficient to allow them to be sold on a competitive basis. Increasingly, third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Significant delays can occur in obtaining reimbursement for newly-approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers a drug company's costs, including research, development, manufacture, sale and distribution.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals, may need to be conducted. Third-party payors may not consider products to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable maintenance of price levels sufficient to realize an appropriate return on a drug company's investment in drug development.

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover a drug company's costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs, (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, which has since been increased to 70% by the BBA, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research, and (ix) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

The current U.S. presidential administration and Congress have, and we expect they will continue to, seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since January 2017, the current U.S. presidential administration has issued two executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of

the requirements for health insurance mandated by the ACA. For example, on October 12, 2017, the current U.S. presidential administration issued an executive order that expands the use of association health plans and allows anyone to purchase short-term health plans that provide temporary, limited insurance. This executive order also calls for the halt of federal payments to health insurers for cost-sharing reductions previously available to lower-income Americans to afford coverage. There is still uncertainty with respect to the impact this executive order could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Reform Act, among other things, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, the current U.S. presidential administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. There is still uncertainty with respect to the impact the current U.S. presidential administration and the Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the MMA changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for

physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the current U.S. presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the current U.S. presidential administration laid out the administration's "Blueprint" to reduce the cost of prescription medications while preserving innovation and cures. While HHS is soliciting feedback on some of these measures, other actions may be immediately implemented by HHS under existing authority. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, Congress and the current U.S. presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Employees

As of November 12, 2019, we had 27 full-time employees. Of these full-time employees, 5 have an M.D. or a Ph.D. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Facilities

Our principal executive office is located in Westlake Village, California, where we lease a total of 4,741 square feet of office space that we use for our administrative, research and development and other activities. The lease expires in July 2021.

Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

MANAGEMENT

Executive Officers, Key Employees and Directors

The following table provides information regarding our executive officers, key employees and directors as of November 12, 2019:

Name	Age	Position(s)
Executive Officers		
Todd Franklin Watanabe	51	Director, President and Chief Executive Officer
John W. Smither	66	Chief Financial Officer
Howard G. Welgus, M.D.	67	Chief Medical Officer
David W. Osborne, Ph.D.	58	Chief Technical Officer
Kenneth A. Lock	46	Chief Commercial Officer
Key Employees		
David Berk, M.D.	41	Vice President, Clinical Development
Scott L. Burrows	42	Vice President, Finance
Meg Elias	54	Vice President, Clinical Operations
Charlotte Merritt	57	Vice President, Regulatory Affairs
Lynn Navale	49	Vice President, Biometrics
Frank Pompilio, Pharm.D.	56	Vice President, Medical Affairs
Non-Employee Directors		
Bhaskar Chaudhuri, Ph.D.	65	Chairman, Director
Alexander G. Asam, Ph.D.	54	Director
Daniel J. Estes, Ph.D.	39	Director
Patrick J. Heron	49	Director
Jonathan T. Silverstein, J.D.	52	Director
Ricky Sun, Ph.D.	46	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Governance Committee.

Executive Officers

Todd Franklin Watanabe has served as our President and Chief Executive Officer since April 2017. Prior to joining Arcutis Biotherapeutics, he served as co-founder and Chief Operating Officer of Kanan Therapeutics, Inc., a cardiovascular drug development company from December 2015 to February 2018, and before that, he served as Vice President of Strategy and Corporate Development at Kythera Biopharmaceuticals Inc. from October 2013 to November 2015. Mr. Watanabe was an executive at Amgen, Inc. from 2005 to 2013, where he was involved in the development of Repatha for hyperlipidemia and Aimovig for migraine, and worked on the U.S. marketing of Enbrel in both dermatology and rheumatology. Previously, he was an executive with Eli Lilly and company, and an official in the U.S. Government. He was also a commissioned officer in the U.S. Navy Reserves for 25 years. Mr. Watanabe received his M.A. in National Security Studies, and his B.A. in International Relations, both from Georgetown University. We believe that Mr. Watanabe is qualified to serve on our board of directors because of his experience with biotechnology companies, including working with and serving in various executive positions in life sciences companies.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

John W. Smither has served as our Chief Financial Officer since May 2019. Mr. Smither previously served as Chief Financial Officer for Sienna Biopharmaceuticals, Inc. from January 2016 to March 2017 and again from April 2018 to April 2019. From October 2017 to March 2018, he was interim Chief Financial Officer for Kite Pharma during its integration with Gilead Sciences, Inc., and prior to that, was Chief Financial Officer at Unity Biotechnology, Inc. from January 2016 to July 2017. Earlier, he served as Chief Financial Officer of Kythera Biopharmaceuticals, Inc. from November 2007, until it was acquired by Allergan plc in October 2015. From 1998 to 2007, Mr. Smither held various positions at Amgen Inc., including head of corporate accounting, vice president of finance and administration for Amgen's European Division and head of internal audit. Prior to joining Amgen, he served as audit partner at Ernst & Young LLP, a public accounting firm, and following his time at Ernst & Young served as Chief Financial Officer of several early stage companies. Mr. Smither currently serves on the board of directors of Achaogen, Inc. Previously, Mr. Smither served on the board of directors of Principia Biopharma Inc. He received a B.S. in Business Administration from California State University, Los Angeles. Mr. Smither is a Certified Public Accountant (inactive) and a member of the American Institute of Certified Public Accountants, the California Society of Certified Public Accountants and Financial Executives.

Howard G. Welgus, M.D. has served as our Chief Medical Officer since April 2017. From February 2016 to June 2018, Dr. Welgus served as the Chief Medical Officer at Verrica Pharmaceuticals Inc. Prior to joining Verrica, Dr. Welgus served as the Chief Medical Officer at Thesan Pharmaceuticals Inc. from September 2012 to November 2016 and served as the Chief Medical Officer at Nycomed US Inc. from May 2009 to November 2010. From 1999 to 2009, he served as the Vice President and head of the Dermatology and Inflammation therapeutic areas at Pfizer Inc. Prior to joining the private sector, Dr. Welgus was a faculty member at Washington University for 17 years. Dr. Welgus is a board-certified dermatologist and received a M.D. from Washington University School of Medicine in St. Louis and a B.A. in Biology from Rice University.

David W. Osborne, Ph.D. has served as our Chief Technical Officer since April 2017 and is one of our cofounders. From April 2008 to May 2016, Dr. Osborne held various positions at Tolmar Inc., including Chief Scientific Officer from December 2013 to May 2016. Prior to joining Tolmar, Dr. Osborne served as Vice President of Product Development at Dow Pharmaceutical Sciences, Inc. from September 2003 to March 2018 and at Atrix Laboratories, Inc. through its acquisition of ViroTex Corp. from 1999 to 2003. He started his career as a formulation group leader at The Upjohn Company and as a Group Leader, Skin Care at Calgon Vestal Laboratories, a subsidiary of Merck & Co., Inc. Dr. Osborne received a B.S. in Chemistry from Missouri State University and a Ph.D. in Physical Chemistry from Missouri University of Science and Technology.

Kenneth A. Lock has served as our Chief Commercial Officer since October 2019. Prior to joining Arcutis, he served as the Executive Director of Sales and Marketing at Gilead Sciences, concurrently leading the Inflammation and Pulmonary Hypertension U.S. commercial franchises from December 2013 to August 2019. Prior to Gilead, Mr. Lock was employed at Amgen, Inc. from March 2007 to November 2013, where he was involved in the prelaunch global development of Repatha for hyperlipidemia and also held U.S. brand marketing and sales leadership roles for Enbrel for Rheumatoid Arthritis and Psoriasis. From June 2003 to February 2007 Mr. Lock was at Wyeth Pharmaceuticals where he held various positions including Strategic Planning, International Commercial Operations, and Marketing for Enbrel in both Rheumatology and Dermatology. He started his career in process development and biologics manufacturing at IDEC Pharmaceuticals in 1996. Mr. Lock received both his B.S. in Biochemistry / Cell Biology and B.A. in Psychology from University of California, San Diego and completed his M.B.A at Cornell University.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

Key Employees

David Berk, M.D. has served as our Vice President, Clinical Development since January 2019. Prior to joining us, Dr. Berk was Executive Director and Section Head for Medical Dermatology at Allergan, Inc. from June 2012 to December 2018. Prior to that, he was in academic practice as an Assistant Professor at Washington University in St. Louis from 2009 to 2012. Dr. Berk is a board-certified Pediatric Dermatologist and completed his Dermatology residency at Washington University in St. Louis and his fellowship training in Pediatric Dermatology at Stanford University. Dr. Berk received a M.D. from Stanford University, and received a A.B. in Molecular Biology from Princeton University.

Scott L. Burrows has served as our Vice President, Finance since May 2019. From March 2018 to May 2019, he was the Head of International Investor Relations for Shire Plc in Zug, Switzerland. Prior to that, Mr. Burrows spent 15 years at Amgen in various Finance roles of increasing responsibility, including Financial Planning & Analysis, Treasury, and Investor Relations. Mr. Burrows started his career as a management consultant with Arthur Andersen in Los Angeles. He received both a B.A. in Business Economics and an M.B.A. from the University of California, Los Angeles and is a Certified Public Accountant (inactive).

Meg Elias has served as our Vice President, Clinical Operations since January 2019. From November 2014 to December 2018, she led the study management group within Clinical Operations at Kite Pharma, and served as the Clinical Operations lead on the pivotal Phase II study which resulted in U.S. and EU market approval of Yescarta. Prior to that, she worked in clinical operations at Amgen from 2003 to 2014 and GlaxoSmithKline from 2000 to 2002. She started her career in clinical nursing, and practiced for 10 years before joining industry. Ms. Elias received a Bachelor of Science in Nursing from Cedar Crest College.

Charlotte Merritt has served as our Vice President, Regulatory Affairs since March 2018. In 2014 she founded PharmaReg Consulting, LLC, where she supported smaller pharma and biotech companies with IND-stage development and preparation of NDAs and where she remains the principal. Previously, she spent more than 20 years at Merck & Co. where she contributed to the global registration of numerous therapies and led strategic and organizational transformation initiatives. Ms. Merritt received a B.S. in Biology from Albright College and an M.B.A. from the John M. Olin School of Business at Washington University in St. Louis.

Lynn Navale has served as our Vice President, Biometrics, since September 2019. From July 2014 to September 2019, she was the Vice President of Biometrics at Kite Pharma, where she developed and led the Biometrics function including biostatistics, statistical programming, and data management and served as the Biometrics team leader for the U.S. and EU regulatory approvals of Yescarta. Previously, from 2003 to 2014, she worked at Amgen in roles of increasing responsibility within Clinical Development Biostatistics. She began her career at Baxter BioScience and was the lead statistician for the trial that led to the U.S. regulatory approval of Advate. Ms. Navale has a B.S. in Math from the University of Michigan and an M.S. in Biostatistics from the University of California Los Angeles.

Frank Pompilio, Pharm.D. has served as our Vice President, Medical Affairs, since October 2019. From June 2016 to October 2019, he was Vice President, Medical Affairs at MannKind Corporation. From October 2014 to June 2016, he was Senior Director, Medical Affairs at Kythera Biopharmaceuticals, Inc. Prior to that, Dr. Pompilio was employed at Amgen, Inc. and Bristol-Myers Squibb, where he worked in medical science and scientific affairs functions from July 1996 to September 2014. While at Amgen, he held various leadership roles supporting the commercialization of Enbrel in both Rheumatology and Dermatology. He started his career as an Assistant Professor at the University of Southern California School of Pharmacy. Dr. Pompilio received a Pharm.D. from USC, a B.S in Pharmacology from the University of California at Santa Barbara, and completed a clinical pharmacy residency at the University of Arizona.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

Non-Employee Directors

Bhaskar Chaudhuri, Ph.D. has served as the chairman of our board of directors since April 2016 and is one of our co-founders. Since June 2011, he has been the Operating Partner at Frazier Healthcare Ventures. Prior to that time, Dr. Chaudhuri served as President of Valeant Pharmaceuticals International, Inc. (currently Bausch Health) from January 2009 to September 2010. Prior to joining Valeant, Dr. Chaudhuri served for seven years as President and Chief Executive Officer of Dow Pharmaceutical Sciences, Inc. and as a member of its board of directors from 2003 to 2008, at which time Dow was acquired by Valeant. Prior to that, Dr. Chaudhuri served as Executive Vice President of Scientific Affairs at Bertek Pharmaceuticals, Inc., a subsidiary of Mylan N.V., from September 2000 to March 2002. Prior to his position at Bertek, Dr. Chaudhuri served as the General Manager of the Dermatology Division of Mylan from September 1998 to August 2000. Dr. Chaudhuri joined Mylan through the acquisition of Penederm, Inc., where he worked from 1992 to 1998 in a number of senior positions before becoming the Vice President of Research and Development. Dr. Chaudhuri serves on the boards of directors of Teligent, Inc., and previously served on the board of directors of Corium International, Inc. He also serves on the Advisory Board of the Johns Hopkins Berman Institute of Bioethics. Dr. Chaudhuri received a B.S. in Pharmacy and a M.S. in Industrial Pharmacy from Jadavpur University and a Ph.D. in Pharmaceutics from the University of Louisiana. We believe Dr. Chaudhuri is qualified to serve on our board of directors because of his many years of experience in the pharmaceutical industry, including his prior positions in senior executive roles at major pharmaceutical companies.

Alexander G. Asam, Ph.D. has served as a member of our board of directors since October 2019. Since 2007, Dr. Asam has been an Investment Advisor of HBM Partners, and brings more than 20 years of experience in the life sciences and private equity businesses. He was a former managing director and partner of Deutsche Venture Capital (DVC) / Deutsche Bank from 2001 to 2007 and held various positions at Hoechst AG, Aventis S.A. (now: Sanofi) and LION Bioscience AG, among others, as well as a member of the IPO Core Team (dual listing Germany and USA). Dr. Asam holds an MBA degree from Aston Business School, Birmingham and a MSc and PhD in chemistry from University of Heidelberg. He is a board member of APR Applied Pharma Research and Sublimity Therapeutics, as well as a board observer at Corvidia Therapeutics, Swixx Biopharma, and Vitaeris. We believe that Dr. Asam is qualified to serve on our board of directors because of his extensive experience in the life sciences industry, including as an investor and board member.

Daniel J. Estes, Ph.D. has served as a member of our board of directors since April 2017. Since April 2011, Dr. Estes has been a member of the investment team and a partner with Frazier Healthcare Partners, where he focuses on investments in both development-stage and commercial-stage pharmaceutical companies. Prior to joining Frazier Healthcare Partners, Dr. Estes served as a management consultant with McKinsey & Company's healthcare practice between 2008 and 2011. Dr. Estes also serves on the board of directors of Sierra Oncology, Inc. Dr. Estes received his Ph.D. in Biomedical Engineering from the University of Michigan and his B.S. in Electrical Engineering from Stanford University. We believe that Dr. Estes is qualified to serve on our board of directors based on his experience in the pharmaceutical and biotechnology industries.

Patrick J. Heron has served as a member of our board of directors since April 2017. Since September 1999, Mr. Heron has been a managing general partner with Frazier Healthcare Partners, where he has been active in company formations and initial investments in various biotechnology companies, including Marcadia Biotech Inc., Calixa Therapeutics, Inc. and VentiRx Pharmaceuticals, Inc. He also led Frazier's involvement in MedPointe Inc. Prior to joining Frazier, Mr. Heron helped develop McKinsey & Company's west coast biotechnology consulting practice. Mr. Heron currently serves on the board of directors of Mirum Pharmaceuticals, Inc. and Iterum Therapeutics plc. He previously served on the boards of directors of the Tobira Therapeutics, Inc. and Collegium

Pharmaceuticals, Inc. Mr. Heron received a B.A. in Political Science from the University of North Carolina at Chapel Hill and an M.B.A. from Harvard Business School. We believe that Mr. Heron is qualified to serve on our board of directors because of his investing and operations experiences in the life sciences industry.

Jonathan T. Silverstein, J.D. has served as a member of our board of directors since August 2018. Mr. Silverstein is currently a Managing Partner and a Co-Head of Global Private Equity at OrbiMed Advisors, a healthcare investment firm, where he has worked since December 1998. Previously, Mr. Silverstein was a director of life sciences in the investment banking department at Sumitomo Bank. Mr. Silverstein currently serves on the board of directors of resTORbio, Inc. and Avedro Inc. Mr. Silverstein has also previously served on the board of directors of Audentes Therapeutics, Inc., Ascendis Pharma A/S, Intercept Pharmaceuticals, Inc., Glaukos Corporation, scPharmaceuticals Inc., Rhythm Pharmaceuticals, Inc. and Sorrento Tech, Inc. (formerly known as Roka BioScience, Inc.). Mr. Silverstein received a B.A. from Denison University and a J.D. and M.B.A. from the University of San Diego. We believe that Mr. Silverstein's strategic development and capital markets experience qualifies him to serve on our board of directors.

Ricky Sun, Ph.D. has served as a member of our board of directors since August 2018. Dr. Sun has been a Partner with Bain Capital Life Sciences since August 2016. From August 2013 to July 2016, he held various positions at Biogen Inc., including Director of Corporate Development and Strategy from January 2015 to July 2016. Prior to Biogen, Dr. Sun served as a Vice President at BlackRock, Inc., as a member of the Fundamental Equity division of BlackRock's Alpha Strategies Group and senior analyst for BlackRock's Fundamental Large Cap Growth equity team, covering the health care sector. Prior to that, he was a senior healthcare analyst at Citadel LLC and Alyeska Investment Group, L.P., in Chicago and worked as a pharmaceuticals equity research analyst on Wall Street, spending time at Lehman Brothers and Morgan Stanley. Dr. Sun received a Ph.D. degree in Chemistry and Chemical Biology from Harvard University, an MBA from New York University Stern School of Business and a B.A. in Chemistry from Berea College. We believe that Dr. Sun's life sciences investment experience qualifies him to serve on our board of directors.

Election of Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.

Board Composition

Our board of directors currently consists of seven members. Six of our directors are independent within the meaning of the independent director guidelines of the Nasdaq Global Select Market, or Nasdaq. Pursuant to our current voting agreement and certificate of incorporation, Todd Franklin Watanabe, Bhaskar Chaudhuri, Alexander G. Asam, Daniel J. Estes, Patrick J. Heron, Jonathan T. Silverstein and Ricky Sun have been designated to serve as members of our board. Jonathan T. Silverstein and Ricky Sun were elected by the holders of our Series B convertible preferred stock. Alexander G. Asam was elected by the holders of our Series C convertible preferred stock. Daniel J. Estes and Patrick J. Heron were elected by the holders of our Series A convertible preferred stock. Todd Franklin Watanabe and Bhaskar Chaudhuri were elected by the holders of our common stock.

The voting agreement and the provisions of our current certificate of incorporation that govern the election and designation of our directors will terminate in connection with this offering, after which no contractual obligations will concern the election of our directors. Each of our current directors will continue to serve until the election and qualification of his successor, or until his earlier death, resignation or removal.

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PURSUANT TO 17 C.F.R. SECTION 200.83**

Classified Board of Directors

Upon the completion of this offering, our board of directors will be divided into three staggered classes of directors. At each annual meeting of stockholders, a class of directors will be subject to re-election for a three-year term. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows:

- the Class I directors will be , and and their terms will expire at the first annual meeting of stockholders held following the completion of the offering;
- the Class II directors will be , and and their terms will expire at the second annual meeting of stockholders held following the completion of the offering; and
- the Class III directors will be , and and their terms will expire at the third annual meeting of stockholders held following the completion of the offering.

Each director's term continues until the election and qualification of his successor, or his earlier death, resignation or removal. Our restated certificate of incorporation and restated bylaws that will be in effect upon the completion of this offering authorize only our board of directors to fill vacancies on our board of directors. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our company. See the section entitled "Description of Capital Stock—Anti-Takeover Provisions—Restated Certificate of Incorporation and Restated Bylaw Provisions."

Director Independence

In connection with this offering, we intend to apply to have our common stock approved for listing on Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within a specified period following the completion of this offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. We intend to satisfy the audit committee independence requirements of Rule 10A-3 as of the completion of this offering. Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determined that all of our directors, except for Todd Franklin Watanabe, are "independent directors" as defined under the applicable rules and regulations of the Securities and

Exchange Commission, or SEC, and the listing requirements and rules of Nasdaq. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain Relationships and Related Party Transactions."

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and governance committee, each of which will have the composition and responsibilities described below as of the completion of this offering. Each of the below committees has a written charter approved by our board of directors. Upon completion of this offering, copies of each charter will be posted on the investor relations section of our website. Members serve on these committees will serve until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee is comprised of , with as the chairman of our audit committee. The composition of our audit committee meets the requirements for independence under the current Nasdaq and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on him any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting and hiring our independent registered public accounting firm;
- the qualifications, independence and performance of our registered public accounting firm;
- the preparation of the audit committee report to be included in our annual proxy statement;
- our compliance with legal and regulatory requirements;
- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements; and
- reviewing and approving related-person transactions.

Compensation Committee

Our compensation committee is comprised of , with as the chairman of our compensation committee. Each member of our compensation committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs;
- evaluating and recommending non-employee director compensation arrangements for determination by our board of directors;
- administering our cash-based and equity-based compensation plans; and

- overseeing our compliance with regulatory requirements associated with the compensation of directors, officers and employees.

Nominating and Governance Committee

Our nominating and governance committee is comprised of , with as the chairman of our nominating and governance committee. Each member of our nominating and governance committee meets the requirements for independence under the current Nasdaq listing standards. Our nominating and governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on other corporate governance matters.

Compensation Committee Interlocks and Insider Participation

None of the current members of our compensation committee has at any time been one of our officers or employees. None of our executive officers has served as a member of the board of directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our board of directors or compensation committee during the year ended December 31, 2018. Prior to establishing the compensation committee, our full board of directors made decisions relating to the compensation of our officers.

Scientific Advisory Board

We have established a scientific advisory board composed of leading academic and industry scientists. We seek advice and input from these scientists on an ad hoc basis, individually or as a group, to provide scientific and clinical feedback and advice related to our research and development platform and programs. The members of our advisory board consist of experts across a range of key disciplines relevant to our programs. Our advisors are not our employees or directors and have no decision-making authority over our activities. Our advisors may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. All of our advisors are affiliated with other entities and devote only a small portion of their time to us. Our advisors receive cash compensation based upon consulting services rendered.

Code of Business Conduct and Ethics

Prior to the completion of this offering, our board of directors will adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and other executive and senior officers. The full text of our code of business conduct and ethics will be posted on the investor relations section of our website. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our website or in public filings to the extent required by the applicable rules.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Non-Employee Director Compensation

The following table presents the total compensation earned by each of our non-employee directors in the year ended December 31, 2018. Our President and Chief Executive Officer, Mr. Watanabe, receives no compensation for his service as a director. Other than as described below, none of our non-employee directors received any fees or reimbursement of any expenses (other than customary expenses in connection with the attendance of meetings of our board of directors) or any equity or non-equity awards in the year ended December 31, 2018.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(2)	Total ($)
Bhaskar Chaudhuri, Ph.D.	200,000(3)	243,982	443,982
Daniel Estes, Ph.D.	—	—	—
Patrick J. Heron	—	—	—
Jonathan T. Silverstein, J.D.	—	—	—
Ricky Sun, Ph.D.	—	—	—
Charlie Stiefel, J.D(4)	—	40,644	40,644

(1) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to the directors during the year ended December 31, 2018 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option Awards column are set forth in Note 9 to the audited financial statements included in this prospectus. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the named executive officers from the options.

(2) The following table sets forth the aggregate number of shares of our common stock subject to outstanding equity awards held by our non-employee directors as of December 31, 2018:

Director name	Number of unvested shares underlying stock awards held as of December 31, 2018	Number of shares underlying options held as of December 31, 2018(A)
Bhaskar Chaudhuri, Ph.D.	202,597(B)	270,129(C)
Daniel Estes, Ph.D.	—	—
Patrick J. Heron	—	—
Jonathan T. Silverstein, J.D.	—	—
Ricky Sun, Ph.D.	—	—
Charlie Stiefel, J.D.	—	90,000(D)

(A) All of the outstanding awards were granted under our 2017 Plan.
(B) This amount reflects stock awards vesting monthly over one and a half years, issued upon the partial early exercise of an option award.
(C) The stock option vests monthly over a two year period beginning June 11, 2020, subject to the holder's continuous provision of services to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to the unvested shares, subject to our right of repurchase. 100% of the options will vest upon a change of control.
(D) The stock option vests monthly over a four year period subject to the holder's continuous service to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to the unvested shares, subject to our right of repurchase. 100% of the options will vest upon a change of control.

(3) Pursuant to an agreement dated August 16, 2016 between us and Mr. Chaudhuri, we pay Mr. Chaudhuri $200,000 to provide services to us as Chair of our board of directors.

(4) Mr. Stiefel resigned from our board of directors on September 5, 2019.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Prior to this offering, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service on our board of directors or committees of our board of directors. In August 2016, we entered into an agreement, or the Chaudhuri Agreement, with Bhaskar Chaudhuri to provide services to us as Chair of our board of directors. Pursuant to the Chaudhuri Agreement, we pay Mr. Chaudhuri an annual fee of $200,000 for his services as a director and chairman of our board of directors.

In connection with this offering, our board of directors expects to approve annual non-employee director compensation, which will take effect following the completion of this offering.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

EXECUTIVE COMPENSATION

The following tables and accompanying narrative disclosure set forth information about the compensation earned by our named executive officers during the year ended December 31, 2018. Our named executive officers, who are our principal executive officer and the two most highly-compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2018, were:

- Todd Franklin Watanabe, President and Chief Executive Officer;
- David W. Osborne, Ph.D., Chief Technical Officer; and
- Howard G. Welgus, M.D., Chief Medical Officer.

Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was awarded to and earned by our named executive officers during the year ended December 31, 2018.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-equity Incentive Plan Compensation ($)(2)	Total($)
Todd Franklin Watanabe *President and Chief Executive Officer*	2018	327,083	180,992(3)	126,000	634,075
David W. Osborne, Ph.D. *Chief Technical Officer*	2018	264,583	104,564(4)	82,500	451,647
Howard G. Welgus, M.D. *Chief Medical Officer*	2018	268,750	52,997(4)	105,000	426,747

(1) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to the named executive officers during the year ended December 31, 2018 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option Awards column are set forth in Note 9 to the audited financial statements included in this prospectus. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the named executive officers from the options.

(2) For additional information regarding the non-equity incentive plan compensation, see "—Non-equity Incentive Plan Awards."

(3) The option vests monthly over a four year period beginning March 1, 2018, subject to the optionee's continuous provision of services to us through each such date. The option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase. In addition to the foregoing vesting arrangements, the option is subject to acceleration upon certain events as described in the section titled "—Employee Offer Letters—2017 Equity Incentive Plan—Change of Control."

(4) The option vests monthly over a four year period beginning June 11, 2018, subject to the optionee's continuous provision of services to us through each such date. The option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase. In addition to the foregoing vesting arrangements, the option is subject to acceleration upon certain events as described in the section titled "—Employee Offer Letters—2017 Equity Incentive Plan—Change of Control."

Non-equity Incentive Plan Awards

Annual bonuses for our executive officers are based on the achievement of corporate and, for all of the executive officers other than our Chief Executive Officer, individual performance objectives. For the 2018 bonuses paid in March 2019, the corporate performance objectives included the delivery of a development candidate, the completion of a target level of financing, and the establishment of

development infrastructure capable of supporting advancement of the development candidates into the clinic. In March 2019, based on the achievement of these corporate performance objectives and satisfaction of individual performance goals, our compensation committee determined to award bonuses equal to 100% of target.

Outstanding Equity Awards at 2018 Fiscal Year-End Table

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2018. All awards were granted under our 2017 Plan.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#) (1)	Market Value of Shares or Units of Stock That Have Not Vested) ($) (2)
Todd Franklin Watanabe	—	—	—	—	415,806(3)	349,277
	—	—	—	—	317,226(4)	266,470
David W. Osborne, Ph.D.	—	—	—	—	202,597(5)	170,181
	—	—	—	—	150,551(6)	126,463
Howard G. Welgus, M.D.(7)	117,352	—	0.29	6/12/2018	—	—

(1) Each option award is subject to the acceleration of vesting provisions in each named executive officer's amended and restated offer letters, as set forth below in the section titled "—Employee Offer Letters."

(2) Market values in these columns were determined by multiplying the number of shares of stock by $0.84, which was the fair market value of our common stock on December 31, 2018, as determined by a third-party valuation firm.

(3) The restricted stock was acquired through the early exercise of a stock option at an exercise price of $0.18 per share. The restricted stock vests monthly over a four year period beginning November 8, 2016, subject to the holder's continuous provision of services to us on each vesting date.

(4) The restricted stock was acquired through the early exercise of a stock option at an exercise price of $0.18 per share. The restricted stock vests monthly over a four year period beginning March 1, 2018, subject to the holder's continuous provision of services to us on each vesting date.

(5) The restricted stock was acquired through the early exercise of a stock option at an exercise price of $0.29 per share. The restricted stock vests monthly over a four year period beginning June 11, 2018, subject to the holder's continuous provision of services to us on each vesting date.

(6) The restricted stock was acquired through the early exercise of a stock option at an exercise price of $0.18 per share. The restricted stock vests monthly over a four year period beginning October 1, 2016, subject to the holder's continuous provision of services to us on each vesting date.

(7) The stock option vests monthly over a four year period beginning June 11, 2018, subject to the holder's continuous provision of services to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase.

Employee Offer Letters

We intend to enter into amended and restated offer letters with each of our named executive officers in connection with the offering. We expect that each of these confirmatory offer letters will provide for at-will employment, will not have a specific term and will include each named executive officer's base salary, a discretionary annual incentive bonus opportunity and standard employee benefit plan participation. These confirmatory offer letters will supersede all existing employment arrangements and understandings. In addition, each of our named executive officers has executed a form of our standard Employee Non-Disclosure, Non-Competition and Assignment of Intellectual Property Agreement.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Potential Payments Upon Termination of Change of Control

We also expect to adopt arrangements for our named executive officers that provide for severance benefits upon certain qualifying terminations of employment, including in connection with a change in control of our company.

Employee Benefit Plans

We believe that our ability to grant equity-based awards is a valuable compensation tool that enables us to attract, retain, and motivate our employees, consultants, and directors by aligning their financial interests with those of our stockholders. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

2017 Equity Incentive Plan

We maintain our 2017 Equity Incentive Plan, as amended, or the 2017 Plan. The purposes of the 2017 Plan are to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to employees, directors and consultants and to promote the success of our business. The material terms of the 2017 Plan are summarized below:

Share Reserve. Subject to adjustment as provided in the 2017 Plan, the maximum number of shares of common stock which may be issued under the 2017 Plan is 7,679,110 shares. 2,191,014 shares remained available for grant under the 2017 Plan as of September 30, 2019. In October 2019, in connection with the issuance of our Series C convertible preferred stock, an additional 2,823,831 shares were authorized to be available for grant under the 2017 Plan. As of September 30, 2019, 2,340,326 options to purchase shares had been exercised and options to purchase 3,147,770 shares remained outstanding, with a weighted average exercise price of $0.80 per share.

Administration. Our 2017 Plan is administered by our board of directors or a committee appointed by our board of directors. Subject to the terms of the 2017 Plan, our board of directors has the authority to, among other things, select the persons to whom awards will be granted, construe and interpret our 2017 Plan as well as to prescribe, amend and rescind rules and regulations relating to the 2017 Plan and awards granted thereunder.

Eligibility. Pursuant to the 2017 Plan, we may grant incentive stock options only to our employees (including officers and directors who are also employees). We may grant non-statutory stock options to our employees (including officers and directors who are also employees), non-employee directors and consultants.

Options. The 2017 Plan provides for the grant of both (i) incentive stock options, which are intended to qualify for tax treatment as set forth under Section 422 of the Internal Revenue Code, as amended, or the Code, and (ii) non-statutory stock options to purchase shares of our common stock, each at a stated exercise price. The exercise price of each stock option must be at least equal to the fair market value of our common stock on the date of grant, unless expressly determined by the board of directors or committee on the date of the grant. However, the exercise price of any incentive stock option granted to an individual who owns more than ten percent of the total combined voting power of all classes of our capital stock must be at least equal to 110% of the fair market value of our common stock on the date of grant.

The maximum permitted term of options granted under our 2017 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual

who owns more than ten percent of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Restricted Stock, Restricted Stock Units and Stock Appreciation Rights. In addition, the 2017 Plan allows for the grant of restricted stock awards, restricted stock units and stock appreciation rights, with terms as generally determined by the administrator (in accordance with the 2017 Plan) and to be set forth in an award agreement. We have not granted any shares of restricted stock, any restricted stock units or any stock appreciation rights under the 2017 Plan and it is not expected that any such awards will be granted prior to the offering.

Limited Transferability. Unless otherwise determined by our board of directors, awards under the 2017 Plan generally may not be transferred or assigned in any manner other than by will or the laws of descent and distribution, or certain gifts to family members.

Change of Control. In the event that we are subject to an "acquisition" or "other combination" (as defined in the 2017 Plan and generally meaning, collectively, a merger, a sale or transfer of more than 50% of the voting power of all of our outstanding securities, or a sale of all or substantially all of our assets), the 2017 Plan provides that awards will be subject to the agreement evidencing such acquisition or other combination, which agreement need not treat all awards in a similar manner. Such agreement may, without the participant's consent, provide for the continuation of outstanding awards, the assumption or substitution of awards, the acceleration of vesting of awards, the settlement of awards (whether or not vested) in cash, securities or other consideration, or the cancellation of such awards for no consideration.

Adjustments. In the event of a stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification, or other change in our capital structure affecting the shares of common stock issued under the 2017 Plan, the number and class of shares that may be delivered under 2017 Plan and/or the number, class and price of shares covered by each outstanding award will (to the extent appropriate) be appropriately adjusted (subject to required action by the board), in order to prevent diminution or enlargement of benefits or potential benefits intended to be made available under the 2017 Plan or otherwise as required by applicable law.

Exchange, repricing and buyout of awards. The administrator may, with the consent of the respective participants, issue new awards in exchange for the surrender and cancelation of any or all outstanding awards. The administrator may also reduce the exercise price of options or stock appreciation rights or buy an award previously granted with payment in cash, shares or other consideration, in each case, subject to the terms of the 2017 Plan.

Amendment/termination. The board of directors may amend or terminate the 2017 Plan at any time and may terminate any and all outstanding options, stock appreciation rights or restricted stock units upon a dissolution or liquidation of us, provided that certain amendments will require shareholder approval. We expect the 2017 Plan will cease issuing awards thereunder upon the effective date of our 2020 Equity Incentive Plan (described below), which is the date immediately prior to the date of the effectiveness of the registration statement of which this prospectus forms a part. Any outstanding awards granted under the 2017 Plan will remain outstanding following the offering, subject to the terms of our 2017 Plan and applicable award agreements, until such awards are exercised or until they terminate or expire by their terms.

2020 Equity Incentive Plan

We intend to adopt our 2020 Equity Incentive Plan, or the 2020 Plan, that will become effective on the date immediately prior to the date of the effectiveness of the registration of which this

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

prospectus forms a part and will serve as the successor to our 2017 Plan. Our 2020 Plan authorizes the award of stock options, restricted stock awards, or RSAs, stock appreciation rights, or SARs, restricted stock units, or RSUs, performance awards and stock bonus awards. We have initially reserved shares of our common stock, plus any reserved shares not issued or subject to outstanding grants under the 2017 Plan on the effective date of the 2020 Plan, for issuance pursuant to awards granted under our 2020 Plan. The number of shares reserved for issuance under our 2020 Plan will increase automatically on January 1 of each of the first ten calendar years during the term of the 2020 Plan by the number of shares equal to the lesser of % of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31, or a number as may be determined by our board of directors.

In addition, the following shares will again be available for issuance pursuant to awards granted under our 2020 Plan:

- shares subject to options or SARs granted under our 2020 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;
- shares subject to awards granted under our 2020 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under our 2020 Plan that otherwise terminate without such shares being issued;
- shares subject to awards granted under our 2020 Plan that are surrendered, cancelled or exchanged for cash or a different award (or combination thereof);
- shares issuable upon the exercise of options or subject to other awards granted under our 2017 Plan that cease to be subject to such options or other awards, by forfeiture or otherwise, after the termination of the 2017 Plan;
- shares subject to awards granted under our 2017 Plan that are forfeited or repurchased by us at the original price after the termination of the 2017 Plan; and
- shares subject to awards under our 2017 Plan or our 2020 Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

Administration. Our 2020 Plan is expected to be administered by our compensation committee, or by our board of directors acting in place of our compensation committee. Subject to the terms and conditions of the 2020 Plan, the compensation committee will have the authority, among other things, to select the persons to whom awards may be granted, construe and interpret our 2020 Plan as well as to determine the terms of such awards and prescribe, amend and rescind the rules and regulations relating to the plan or any award granted thereunder. The 2020 Plan provides that the board or compensation committee may delegate its authority, including the authority to grant awards, to one or more executive officers to the extent permitted by applicable law, provided that awards granted to non-employee directors may only be determined by our board of directors.

Eligibility. Our 2020 Plan provides for the grant of awards to our employees, directors, consultants, independent contractors and advisors. No non-employee director may receive awards under our 2020 Plan that, when combined with cash compensation received for services as a non-employee director, exceed $ in a calendar year or $ in the calendar year of his or her initial services as a non-employee director with us.

Options. The 2020 Plan provides for the grant of both incentive stock options intended to qualify under Section 422 of the Code, and non-statutory stock options to purchase shares of our common

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

stock at a stated exercise price. Incentive stock options may only be granted to employees, including officers and directors who are also employees. The exercise price of stock options granted under the 2020 Plan must be at least equal to the fair market value of our common stock on the date of grant. Incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock must have an exercise price of at least 110% the fair market value of our common stock on the date of grant. Subject to stock splits, dividends, recapitalizations or similar events, no more than shares may be issued pursuant to the exercise of incentive stock options granted under the 2020 Plan.

Options may vest based on service or achievement of performance conditions. Our compensation committee may provide for options to be exercised only as they vest or to be immediately exercisable, with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. The maximum term of options granted under our 2020 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Restricted Stock Awards. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the compensation committee. Holders of RSAs, unlike holders of options, will have the right to vote and any dividends or stock distributions paid pursuant to RSAs will be accrued and paid when the restrictions on such shares lapse. Unless otherwise determined by the compensation committee at the time of award, vesting will cease on the date the participant no longer provides services to us and unvested shares may be forfeited to or repurchased by us.

Stock Appreciation Rights. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by our compensation committee), to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The exercise price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may vest based on service or achievement of performance conditions, and may not have a term that is longer than ten years from the date of grant.

Restricted Stock Units. RSUs represent the right to receive shares of our common stock at a specified date in the future, and may be subject to vesting based on service or achievement of performance conditions. Payment of earned RSUs will be made as soon as practicable on a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both. No RSU may have a term that is longer than ten years from the date of grant.

Performance Awards. Performance awards granted to pursuant to the 2020 Plan may be in the form of a cash bonus, or an award of performance shares or performance units denominated in shares of our common stock that may be settled in cash, property or by issuance of those shares subject to the satisfaction or achievement of specified performance conditions.

Stock Bonus Awards. A stock bonus award provides for payment in the form of cash, shares of our common stock or a combination thereof, based on the fair market value of shares subject such award as determined by our compensation committee. The awards may be granted as consideration for services already rendered, or at the discretion of the compensation committee, may be subject to vesting restrictions based on continued service or performance conditions.

Cash Awards. A cash award is an award that is denominated in, or payable to an eligible participant solely in, cash.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Dividend Equivalents Rights. Dividend equivalent rights may be granted at the discretion of our compensation committee, and represent the right to receive the value of dividends, if any, paid by us in respect of the number of shares of our common stock underlying an award. Dividend equivalent rights will be subject to the same vesting or performance conditions as the underlying award and will be paid only at such time as the underlying award has become fully vested. Dividend equivalent rights may be settled in cash, shares or other property, or a combination of thereof as determined by the compensation committee.

Change of Control. In the event of a corporate transaction (as defined in the 2020 Plan) awards may be assumed, converted, replaced, or substituted by the successor corporation, which assumption, conversion, replacement or substitution will be binding on all participants. In the event of a substitution, the successor corporation may substitute equivalent awards or provide substantially similar consideration to participants as was provided to stockholders (after taking into account the existing provisions of the awards). In the event such successor or acquiring corporation (if any) refuses to assume, convert, replace, or substitute awards, as provided above, pursuant to a corporate transaction, then notwithstanding any other provision in the 2019 Plan to the contrary, such awards shall have their vesting accelerate as to all shares or cash subject to such awards (and any applicable right of repurchase shall fully lapse) immediately prior to the corporate transaction and all such awards shall expire on such corporate transaction at such time and on such conditions as our board of directors determine. In addition, in the event such successor or acquiring corporation (if any) refuses to assume, convert, replace, or substitute awards, as provided above, pursuant to a corporate transaction, the committee will notify the participant in writing or electronically that such participant's Award will, if exercisable, be exercisable for a period of time determined by the committee in its sole discretion, and such award will terminate upon the expiration of such period. Awards need not all be treated in the same manner in a corporate transaction, and treatment may vary from award to award and/or from participant to participant.

Adjustment. In the event of a change in the number of outstanding shares of our common stock without consideration by reason of a stock dividend, extraordinary dividend or distribution, recapitalization, stock split, reverse stock split, subdivision, combination, consolidation reclassification, spin-off or similar change in our capital structure, appropriate proportional adjustments will be made to the number of shares reserved for issuance under our 2020 Plan; the exercise prices, number and class of shares subject to outstanding options or SARs; the number and class of shares subject to other outstanding awards; and any applicable maximum award limits with respect to incentive stock options.

Clawback; Transferability. All awards will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by our board of directors or required by law during the term of service of the award holder, to the extent set forth in such policy or applicable agreement. Except in limited circumstances, awards granted under our 2020 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

Amendment and Termination. Our board of directors may amend our 2020 Plan at any time, subject to stockholder approval as may be required. Our 2020 Plan will terminate ten years from the date our board of directors adopts the plan, unless it is terminated earlier by our board of directors. No termination or amendment of the 2020 Plan may adversely affect any then-outstanding award without the consent of the affected participant, except as is necessary to comply with applicable laws.

2020 Employee Stock Purchase Plan

We intend to adopt a 2020 Employee Stock Purchase Plan, or ESPP, that will become effective upon the effectiveness of the registration statement of which this prospectus forms a part in order to

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

enable eligible employees to purchase shares of our common stock with accumulated payroll deductions. Our ESPP is intended to qualify under Section 423 of the Code.

Shares Available. We have initially reserved shares of our common stock for sale under our ESPP. The aggregate number of shares reserved for sale under our ESPP will increase automatically on January 1st of each of the first ten calendar years after the first offering date by the number of shares equal to the lesser of % of the total outstanding shares of our common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by our board of directors in any particular year. The aggregate number of shares issued over the term of our ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed shares of our common stock.

Administration. Our compensation committee will administer our ESPP subject to the terms and conditions of the ESPP. Among other things, the compensation committee will have the authority to determine eligibility for participation in the ESPP, designate separate offerings under the plan, and construe, interpret and apply the terms of the plan.

Eligibility. Employees eligible to participate in any offering pursuant to the ESPP generally include any employee that is employed by us or certain of our designated subsidiaries at the beginning of the offering period. However, our compensation committee may determine that employees who are customarily employed for 20 hours or less per week or for five months or less in a calendar year may not be eligible to participate in the ESPP. In addition, any employee who owns (or is deemed to own as a result of attribution) 5% or more of the total combined voting power or value of all classes of our capital stock, or the capital stock of one of our qualifying subsidiaries, or who will own such amount as a result of participation in the ESPP, will not be eligible to participate in the ESPP. The compensation committee may impose additional restrictions on eligibility from time to time.

Offerings. Under our ESPP, eligible employees will be offered the option to purchase shares of our common stock at a discount over a series of offering periods. Each offering period may itself consist of one or more purchase periods. No offering period may be longer than 27 months.

Participation. Participating employees will be able to purchase the offered shares of our common stock by accumulating funds through payroll deductions. Participants may select a rate of payroll deduction between 1% and 15% of their eligible compensation. However, a participant may not subscribe for more than $25,000 in fair market value of shares of our common stock (determined as of the date the offering period commences) in any calendar year in which the offering is in effect. In addition, no participant will be permitted to purchase more than shares during any one purchase period or such greater or lesser amount determined by our compensation committee, in its discretion.

The purchase price for shares of our common stock purchased under the ESPP will be 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of each purchase period in the applicable offering period.

Once an employee becomes a participant in an offering period, the participant will be automatically enrolled in each subsequent offering period at the same contribution level. A participant may reduce his or her contribution in accordance with procedures set forth by the compensation committee and may withdraw from participation in the ESPP at any time prior the end of an offering period, or such other time as may be specified by the compensation committee. Upon withdrawal, the accumulated payroll deductions will be returned to the participant without interest.

Adjustments upon Recapitalization. If the number of outstanding shares of our common stock is changed by stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination,

reclassification or similar change in our capital structure without consideration, then our compensation committee will proportionately adjust the number and class of common stock that is available under the ESPP, the purchase price and number of shares any participant has elected to purchase as well as the maximum number of shares which may be purchased by participants.

Change of Control. If we experience a change of control transaction, any offering period that commenced prior to the closing of the proposed change of control transaction will be shortened and terminated on a new purchase date. The new purchase date will occur on or prior to the closing of the proposed change of control transaction, and our ESPP will then terminate on the closing of the proposed change of control.

Transferability. A participant may not assign, transfer, pledge or otherwise dispose of payroll deductions credited to his or her account, or any rights with regard to an election to purchase shares pursuant to the ESPP other than by will or the laws of descent or distribution.

Amendment; Termination. The compensation committee may amend, suspend or terminate the ESPP at any time without stockholder consent, except as required by law. Our ESPP will continue until the earlier to occur of (a) termination of the ESPP by the Board, (b) issuance of all of the shares reserved for issuance under the ESPP, or (c) the tenth anniversary of the effective date under the ESPP.

401(k) Plan

We sponsor a retirement savings plan that is intended to qualify for favorable tax treatment under Section 401(a) of the Code, and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. Participants may make pre-tax and certain after-tax (Roth) salary deferral contributions to the plan from their eligible earnings up to the statutorily prescribed annual limit under the Code. Participants who are 50 years of age or older may contribute additional amounts based on the statutory limits for catch-up contributions. Participant contributions are held in trust as required by law. No minimum benefit is provided under the plan. An employee's interest in his or her salary deferral contributions is 100% vested when contributed. We do not match contributions.

Other Benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

Limitations on Liability and Indemnification Matters

Our restated certificate of incorporation that will become effective in connection with the completion of this offering contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Our restated certificate of incorporation and our restated bylaws that will become effective in connection with the completion of this offering require us to indemnify our directors and officers to the maximum extent not prohibited by the DGCL and allow us to indemnify other employees and agents as set forth in the DGCL.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors, officers and certain of our key employees, in addition to the indemnification provided for in our restated certificate of incorporation and restated bylaws. These agreements, among other things, require us to indemnify our directors, officers and key employees for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to us or any of our subsidiaries or any other company or enterprise to which these individuals provide services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted.

We believe that these indemnification provisions and agreements are necessary to attract and retain qualified directors, officers and key employees. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our restated certificate of incorporation and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, executive officers or persons controlling us, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements, including employment agreements, with our directors and executive officers, including those discussed in the section entitled "Executive Compensation," the following is a description of each transaction since January 1, 2017 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of our total assets; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which are described where required under the section entitled "Executive Compensation."

Series C Convertible Preferred Stock Financing

In October 2019, we sold an aggregate of 16,251,628 shares of our Series C convertible preferred stock at a purchase price of $5.8148 per share for an aggregate gross purchase price of approximately $94.5 million. Each share of our Series C convertible preferred stock will convert automatically into one share of our common stock upon the completion of this offering.

The purchasers of our Series C convertible preferred stock are entitled to specified registration rights. For additional information, see "Description of Capital Stock—Registration Rights." The following table summarizes the Series C convertible preferred stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series C convertible preferred stock. Please refer to the section titled "Principal Stockholders" for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series C Convertible Preferred Stock	Total Purchase Price ($)
Bain Capital Life Sciences Fund, L.P.(1)	1,560,062	9,071,449
BCIP Life Sciences Associates, LP(1)	159,687	928,548
Frazier Life Sciences VIII, L.P.(2)	2,149,687	12,500,000
OrbiMed Private Investments VII, LP(3)	1,719,749	9,999,996
OrbiMed Partners Master Fun, Ltd(3)	859,874	4,999,995
HBM Healthcare Investments (Cayman), Ltd.(4)	2,579,624	14,999,998

(1) Ricky Sun, a member of our board of directors, is a Partner at Bain Capital Life Sciences Investors, LLC. The Bain entities hold an aggregate of more than 5% of our outstanding capital stock.

(2) Daniel J. Estes and Patrick J. Heron, both members of our board of directors, is a Partner and the Managing General Partner, respectively, at Frazier Health Life Sciences. Frazier Life Sciences VIII, L.P. holds more than 5% of our outstanding capital stock.

(3) Jonathan T. Silverstein, a member of our board of directors, is a Managing Partner and Co-Head of Global Private Equity at OrbiMed Advisors LLC. OrbiMed Private Investments VII, LP, or OPI VII, holds more than 5% of our outstanding capital stock. OrbiMed Capital GP VII LLC, or OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors LLC, or OrbiMed Advisors, a registered investment advisor under the Investment Advisors Act of 1940, as amended, is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be

deemed to have voting and investment power over the securities held by OPI VII and as a result may be deemed to have beneficial ownership over such securities. OrbiMed Partners Master Fund Limited, or OPMF, holds 859,874 of our outstanding capital stock. OrbiMed Capital LLC, or OrbiMed Capital, is the sole holder of manager shares and sole voting member of OPMF. OrbiMed Capital is a relying adviser of OrbiMed Advisors. OrbiMed Advisors and OrbiMed Capital exercise voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI VII and OPMF.

(4) Alexander G. Asam, a member of our board of directors, is an investment advisor to HBM Partners AG. HBM Partners AG acts as an investment advisor to HBM Healthcare Investments (Cayman) Ltd. Dr. Asam has no voting or investment power over the shares held by HBM Healthcare Investments (Cayman) Ltd. and disclaims beneficial ownership of such shares.

Series B Convertible Preferred Stock Financing

In September 2018, we sold an aggregate of 18,736,267 shares of our Series B convertible preferred stock at a purchase price of $3.0956 per share for an aggregate purchase price of approximately $58.0 million. Each share of our Series B convertible preferred stock will convert automatically into one share of our common stock upon the completion of this offering.

The purchasers of our Series B convertible preferred stock are entitled to specified registration rights. For additional information, see “Description of Capital Stock—Registration Rights.” The following table summarizes the Series B convertible preferred stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series B convertible preferred stock. Please refer to the section titled “Principal Stockholders” for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series B Convertible Preferred Stock	Total Purchase Price ($)
Bain Capital Life Sciences Fund, L.P.(1)	5,128,258	15,875,035
BCIP Life Sciences Associates, LP(1)	524,926	1,624,961
Frazier Life Sciences VIII, L.P.(2)	4,199,508	12,999,997
OrbiMed Private Investments VII, LP(3)	5,653,185	17,499,999

(1) Ricky Sun, a member of our board of directors, is a Partner at Bain Capital Life Sciences Investors, LLC. The Bain entities hold an aggregate of more than 5% of our outstanding capital stock.

(2) Daniel J. Estes and Patrick J. Heron, both members of our board of directors, is a Partner and the Managing General Partner, respectively, at Frazier Health Life Sciences. Frazier Life Sciences VIII, L.P. holds more than 5% of our outstanding capital stock.

(3) Jonathan T. Silverstein, a member of our board of directors, is a Managing Partner and Co-Head of Global Private Equity at OrbiMed Advisors LLC. OrbiMed Private Investments VII, LP, or OPI VII, holds more than 5% of our outstanding capital stock. OrbiMed Capital GP VII LLC, or OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors LLC, or OrbiMed Advisors, a registered investment adviser under the Investment Advisors Act of 1940, as amended, is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by OPI VII and as a result may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein. Each of OrbiMed GP VII, OrbiMed Advisors, Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein disclaims beneficial ownership of the shares held by OPI VII, except to the extent of its or his pecuniary interest therein if any.

Series A Convertible Preferred Stock Financing

In two closings in April 2017 and March 2018, we sold an aggregate of 13,500,000 shares of our Series A convertible preferred stock at a purchase price of $1.00 per share for an aggregate purchase price of approximately $13.5 million. In addition, we issued an aggregate of 300,000 shares of our Series A convertible preferred stock to certain holders of convertible promissory notes. Each share of our Series A convertible preferred stock will convert automatically into one share of our common stock upon the completion of this offering.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

The purchasers of our Series A convertible preferred stock are entitled to specified registration rights. For additional information, see “Description of Capital Stock—Registration Rights.” The following table summarizes the Series A convertible preferred stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series A convertible preferred stock. Please refer to the section titled “Principal Stockholders” for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series A Convertible Preferred Stock	Total Purchase Price ($)
Bhaskar Chaudhuri(1)	75,000	37,500
Chaudhuri Family Trust(2)	100,000	100,000
David W. Osborne(3)	50,000	50,000
Frazier Life Sciences VIII, L.P.(4)	12,725,000	12,612,500
Todd Franklin Watanabe(5)	200,000	200,000
Watanabe Ventures, LLC(5)	100,000	100,000
Welgus Living Trust(6)	50,000	50,000

(1) Bhaskar Chaudhuri is the chair of our board of directors. Consists of 75,000 shares of Series A Preferred Stock from cancellation of indebtedness of a convertible promissory note held by Mr. Chaudhuri. Such shares are calculated by multiplying the dollar amount of the indebtedness cancelled by the discounted price of $0.50 per share applicable to cancellation of indebtedness.
(2) Bhaskar Chaudhuri is the chair of our board of directors and is the trustee of the Chaudhuri Family Trust.
(3) David W. Osborne is our Chief Technical Officer.
(4) Daniel J. Estes and Patrick J. Heron, both members of our board of directors, is a Partner and the Managing General Partner, respectively, at Frazier Health Life Sciences. Frazier Life Sciences VIII, L.P. holds more than 5% of our outstanding capital stock. Includes 225,000 shares of Series A Preferred Stock from cancellation of indebtedness of a convertible promissory note held by Frazier Life Sciences VIII, L.P. Such shares are calculated by multiplying the dollar amount of the indebtedness cancelled by the discounted price of $0.50 per share applicable to cancellation of indebtedness.
(5) Todd Franklin Watanabe is our President and Chief Executive Officer and a member of our board of directors. Mr. Watanabe is the Chief Operating Officer of Watanabe Ventures, LLC.
(6) Howard G. Welgus is our Chief Medical Officer and a trustee of the Welgus Living Trust.

Convertible Note Financing

In August 2016, we issued convertible promissory notes to Bhaskar Chaudhuri and Frazier Life Sciences VIII, L.P. in an aggregate principal amount of $150,000. In April 2017, the convertible promissory notes were extinguished and the entire principal amounts thereof were converted into an aggregate of 300,000 shares of our Series A convertible preferred stock.

Transactions with Hawkeye Therapeutics, Inc.

In June 2019, we entered into a collaboration agreement, or the Hawkeye Agreement, with Hawkeye Therapeutics, Inc., or Hawkeye, to collaborate on the research and development of one or more new applications of roflumilast. In consideration for their services to be performed under the Hawkeye Agreement, each of Arcutis Biotherapeutics, David W. Osborne, our Chief Technical Officer, and Bhaskar Chaudhuri, the chair of our board of directors, purchased 995,000, 250,000 and 500,000 shares of common stock in Hawkeye, respectively, pursuant to a stock purchase agreement. Additionally, one of our stockholders, Frazier Life Sciences VIII, L.P., is a stockholder in Hawkeye, and Bhaskar Chaudhuri, Daniel J. Estes and Patrick J. Heron, each a member of our board of directors, are affiliated with Frazier Life Sciences VIII, L.P. For more information, please see Note 6 to the interim condensed financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Investors' Rights Agreement

We have entered into an amended and restated investors' rights agreement, dated September 6, 2018, with certain holders of our convertible preferred stock, including entities with which certain of our executive officers and directors are affiliated. These stockholders are entitled to rights with respect to the registration of their shares following this offering under the Securities Act. For a description of these registration rights, see the section entitled "Description of Capital Stock—Registration Rights."

Equity Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain directors, as more fully described in the sections entitled "Executive Compensation" and "Management—Non-Employee Director Compensation," respectively.

Director and Executive Officer Compensation

Please see the sections entitled "Management—Non-Employee Director Compensation" and "Executive Compensation" for information regarding the compensation of our directors and executive officers.

Employment Agreements

We intend to enter into amended and restated employment offer letters with our executive officers. For more information regarding these agreements, see the section entitled "Executive Compensation—Employee Offer Letters."

Indemnification Agreements

In connection with this offering, we intend to enter into new indemnification agreements with each of our directors and executive officers. The indemnification agreements, our restated certificate of incorporation and our restated bylaws will require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and officers. For more information regarding these agreements, see the section entitled "Executive Compensation—Limitations on Liability and Indemnification Matters" for information on our indemnification arrangements with our directors and executive officers.

Policies and Procedures for Related Party Transactions

In connection with this offering, we intend to adopt a written related person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. We expect the policy to provide that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate family members or affiliates in which the amount involved exceeds $120,000 will be presented to our audit committee

(or the committee composed solely of independent directors, if applicable) for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee (or the committee composed solely of independent directors, if applicable) will consider the relevant facts and circumstances available and deemed relevant to the audit committee (or the committee composed solely of independent directors, if applicable), including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

PRINCIPAL STOCKHOLDERS

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of our common stock at October 10, 2019, and as adjusted to reflect the shares of common stock to be issued and sold in this offering, for:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who beneficially owned more than 5% of our outstanding shares of common stock.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Beneficial ownership prior to this offering is based on 54,522,960 shares of common stock outstanding as of October 10, 2019, including 1,777,301 shares of unvested common stock subject to repurchase, assuming the conversion of all outstanding shares of our convertible preferred stock, including 16,251,628 shares of Series C convertible preferred stock issued in October 2019, into 48,787,895 shares of our common stock. Beneficial ownership after this offering is based on shares of common stock outstanding immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares of common stock from us and assuming none of the holders listed therein have purchased shares in the offering.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of October 10, 2019. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Arcutis Biotherapeutics, Inc., 2945 Townsgate Road, Suite 110, Westlake Village, CA 91361.

	Beneficial Ownership Prior to this Offering		Beneficial Ownership After this Offering	
Name of Beneficial Owner	**Number**	**Percent**	**Number**	**Percent**
Directors and Named Executive Officers:				
Todd Franklin Watanabe(1)	2,250,861	4.1%		%
David W. Osborne, Ph.D.(2)	890,750	1.6		
John W. Smither(3)	550,000	1.0		
Howard G. Welgus, M.D.(4)	675,438	1.2		
Bhaskar Chaudhuri, Ph.D.(5)	2,103,417	3.8		
Daniel J. Estes, Ph.D.(6)	20,092,617	36.9		
Patrick J. Heron(7)	20,092,617	36.9		
Jonathan T. Silverstein, J.D.(8)	8,232,808	15.1		
Ricky Sun, Ph.D.(9)	—	—		
Alexander G. Asam, Ph.D.(10)	—	—		
All executive officers and directors as a group (10 persons)(11)	34,795,891	61.7		
5% or Greater Stockholders:				
Bain Capital Life Sciences Entities(12)	7,372,933	13.5		
Frazier Life Sciences VIII, L.P.(13)	20,092,617	36.9		
OrbiMed Private Investments VII, LP(14)	8,232,808	15.1		

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

* Represents beneficial ownership of less than one percent.

(1) Consists of (i) 1,207,233 shares of our common stock held of record by Todd Franklin Watanabe, (ii) 100,000 shares of our common stock held of record by Watanabe Ventures, LLC, (iii) 35,714 shares of our common stock held of record by The Anderson Prest Watanabe Irrevocable Trust dated 12 December 2006, (iv) 35,714 shares of our common stock held of record by The John Franklin Watanabe Trust dated 25 July 2001, and (v) 872,200 shares of our common stock subject to options that are exercisable within 60 days of October 10, 2019, all of which shares are unvested, but early exercisable.

(2) Consists of (i) 540,750 shares of our common stock held of record by David W. Osborne, (ii) 125,000 shares of our common stock held of record by The Osborne Irrevocable Trust FBO John Osborne, dated July 1, 2019, (iii) 125,000 shares of our common stock held of record by The Osborne Irrevocable Trust FBO Sharon Osborne, dated July 1, 2019, and (iv) 100,000 shares of our common stock subject to options that are exercisable within 60 days of October 10, 2019, all of which are unvested, but early exercisable.

(3) Consists of (i) 200,000 shares of our common stock held of record by John W. Smither and (ii) 350,000 shares of our common stock subject to options that are exercisable within 60 days of October 10, 2019, all of which are unvested, but early exercisable.

(4) Consists of (i) 289,868 shares of our common stock held of record by Howard G. Welgus, (ii) 50,000 shares of our common stock held of record by the Welgus Living Trust, UA 02-15-2011, and (iii) 335,570 shares of our common stock subject to options that are exercisable within 60 days of October 10, 2019, of which 290,382 shares are unvested, but early exercisable.

(5) Consists of (i) 1,803,417 shares of our common stock held of record by Bhaskar Chaudhuri, (ii) 100,000 shares of our common stock held of record by the Chaudhuri Family Trust Dated January 12, 2001, and (ii) 200,000 shares of our common stock subject to options that are exercisable within 60 days of October 10, 2019, all of which are unvested.

(6) Daniel J. Estes is a Partner at Frazier Healthcare Partners. See footnote 6. Dr. Estes disclaims beneficial ownership of the shares held by FLS LP.

(7) Consists of 20,092,617 shares of our common stock held by Frazier Life Sciences VIII, LP, or FLS LP. The general partner of FLS LP is FHM Life Sciences VIII, LP, or FHM LP. The general partner of FHM LP is FHM Life Sciences VIII, LLC. James Topper and Patrick J. Heron are the sole managing members of FHM Life Sciences VIII, LLC and share voting and investment power with respect to such shares held by FLS LP. Dr. Topper and Mr. Heron disclaim beneficial ownership of such shares except to the extent of their pecuniary interest in such shares. The principal business address of FLS LP is Two Union Square, 601 Union Street, Suite 3200, Seattle, WA 98101.

(8) Jonathan T. Silverstein is a member of OrbiMed Advisors LLC and a member of our board of directors. See footnote 13.

(9) Does not include shares of common stock held by the Bain Capital Life Sciences Entities (as defined below). Ricky Sun is a Partner with Bain Capital Life Sciences Investors, LLC.

(10) Does not include shares held by HBM Healthcare Investments (Cayman) Ltd. Alexander G. Asam is an investment advisor to HBM Partners AG. HBM Partners AG acts as an investment advisor to HBM Healthcare Investments (Cayman) Ltd. Dr. Asam has no voting or investment power over the shares held by HBM Healthcare Investments (Cayman) Ltd. and disclaims beneficial ownership of such shares.

(11) Includes 1,857,770 shares subject to options held by all executive officers and directors that are exercisable within 60 days of October 10, 2019, of which 1,812,582 shares are unvested, but early exercisable.

(12) Consists of (i) 6,688,320 shares of our common stock held by Bain Capital Life Sciences Fund, L.P., or BC LS, and (ii) 684,613 shares of our common stock held by BCIP Life Sciences Associates, LP, or BCIP LS, and together with BC LS, the Bain Capital Life Sciences Entities. Bain Capital Life Sciences Investors, LLC, whose managers are Jeffrey Schwartz and Adam Koppel, is the ultimate general partner of BC LS and governs the investment strategy and decision-making process with respect to investments held by BCIP LS. AS a result, each of Bain Capital Life Sciences Investors, LLC, Mr. Schwartz and Dr. Koppel may be deemed to share voting and dispositive power over the shares held by the Bain Capital Life Sciences Entities. The address of the Bain Capital Life Sciences Entities is c/o Bain Capital Life Sciences, LP, 200 Calerndon Street, Boston, MA 02116.

(13) Consists of 20,092,617 shares of our common stock held by Frazier Life Sciences VIII, LP, or FLS LP. The general partner of FLS LP is FHM Life Sciences VIII, LP, or FHM LP. The general partner of FHM LP is FHM Life Sciences VIII, LLC. James Topper and Patrick J. Heron are the sole managing members of FHM Life Sciences VIII, LLC and share voting and investment power with respect to such shares held by FLS LP. Dr. Topper and Mr. Heron disclaim beneficial ownership of such shares except to the extent of their pecuniary interest in such shares. The principal business address of FLS LP is Two Union Square, 601 Union Street, Suite 3200, Seattle, WA 98101.

(14) Consists of (i) 7,372,934 shares of our common stock held by OrbiMed Private Investments VII, LP, or OPI VII, and (ii) 859,874 shares of our common stock held by OrbiMed Partners Master Fund Limited, or OPMF. OrbiMed Capital GP VII LLC, or OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors LLC, or OrbiMed Advisors, a registered investment advisor under the Investment Advisors Act of 1940, as amended, is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by OPI VII and as a result may be deemed to have beneficial ownership over such securities. OrbiMed Capital LLC, or OrbiMed Capital, is the sole holder of manager shares and sole voting member of OPMF. OrbiMed Capital is a relying adviser of OrbiMed Advisors. OrbiMed Advisors and OrbiMed Capital exercise voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI VII and OPMF. The business address of these entities is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

DESCRIPTION OF CAPITAL STOCK

The following description summarizes the most important terms of our capital stock, as they will be in effect following this offering. Because it is only a summary, it does not contain all the information that may be important to you. We expect to adopt a restated certificate of incorporation and restated bylaws that will become effective upon the completion of this offering, and this description summarizes provisions that are expected to be included in these documents. For a complete description, you should refer to our restated certificate of incorporation and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

General

Upon the completion of this offering, our authorized capital stock will consist of shares of common stock, $0.0001 par value per share, and shares of undesignated preferred stock, $0.0001 par value per share.

Pursuant to the provisions of our current certificate of incorporation all of the outstanding convertible preferred stock will convert into common stock in connection with the completion of this offering. Our Series Seed Series A, Series B and Series C convertible preferred stock will each convert at a ratio of 1:1. Assuming the effectiveness of this conversion as of October 10, 2019, there were 54,522,960 shares of our common stock issued, held by approximately 30 stockholders of record, and no shares of our convertible preferred stock outstanding. Our board of directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

Common Stock

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section entitled “Dividend Policy.”

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation, which means that holders of a majority of the shares of our common stock will be able to elect all of our directors. Our restated certificate of incorporation will establish a classified board of directors, to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any

participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

Immediately prior to the completion of this offering, each outstanding share of preferred stock will be converted into one share of common stock.

Following the completion of this offering, our board of directors will be authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors will also be able to increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

Stock Options

As of September 30, 2019, we had outstanding options to purchase an aggregate 3,147,770 shares of our common stock, with an average exercise price of $0.80.

Registration Rights

Pursuant to the terms of our amended and restated investors' rights agreement, or IRA, immediately following this offering, the holders of shares of our common stock will be entitled to rights with respect to the registration of these shares under the Securities Act, as described below. We refer to these shares collectively as registrable securities.

Form S-1 Registration Rights

Beginning 180 days after the completion of this offering, the holders of at least 10% of the then-outstanding registrable securities may make a request to us for the registration under the Securities Act of registrable securities if the aggregate price to the public of the shares offered is at least $10.0 million. Within ten (10) days following such request, we are obligated to provide notice of such request to all stockholders, other than the initiating holders, to file a registration statement under the Securities Act covering all registrable securities that the initiating holders requested to be registered and any additional registrable securities requested to be included in such registration by any other holders. We are only required to file two registration statements that are declared effective upon exercise of these demand registration rights. We may postpone taking action with respect to such filing not more than once during any 12-month period for a total period of not more than 90 days, if after receiving a request for registration, we furnish to the holders requesting such registration a certificate signed by our Chief Executive Officer stating that, in the good faith judgment of our board of directors, it would materially interfere with a corporate transaction, require premature disclosure of confidential information or render us unable to comply with the Securities Act or Exchange Act.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

The underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned, in proportion (as nearly as practicable), to the number of registrable securities owned by each holder or in such other proportion as shall mutually be agreed to by all such selling holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities are first entirely excluded from the underwriting.

Form S-3 Registration Rights

Any holder or group of holders of at least 10% of then-outstanding registrable securities can request that we register all or part of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least $1.0 million. The stockholders may only require us to effect two registration statements on Form S-3 in a 12-month period. We may postpone taking action with respect to such filing not more than once during any 12-month period for a total period of not more than 90 days, if after receiving a request for registration, we furnish to the holders requesting such registration a certificate signed by our Chief Executive Officer stating that, in the good faith judgment of our board of directors, it would materially interfere with a corporate transaction, require premature disclosure of confidential information or render us unable to comply with the Securities Act or Exchange Act.

The underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned, in proportion (as nearly as practicable), to the number of registrable securities owned by each holder or in such other proportion as shall mutually be agreed to by all such selling Holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities are first entirely excluded from the underwriting.

Piggyback Registration Rights

If we register any of our securities for public sale, holders of then-outstanding registrable securities or their permitted transferees will have the right to include their registrable securities in the registration statement. However, this right does not apply to a registration relating to any of our employee benefit plans, a corporate reorganization or transaction under Rule 145 of the Securities Act, a registration that requires information that is not substantially the same, or a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered. In an underwritten offering, if the total number of securities requested by stockholders to be included in the offering exceeds the number of securities to be sold (other than by the us) that the underwriters determine in their reasonable discretion is compatible with the success of the offering, then we will be required to include only that number of securities that the underwriters and us, in our sole discretion, determine will not jeopardize the success of the offering. If the underwriters determine that less than all the securities requested to be registered cab be included in the offering, the number of shares to be registered will be apportioned pro rata among the selling holders, according to the total number of registrable securities owned by each holder, or in a manner mutually agreed upon by all such selling holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities (other than the securities to be sold by us) are excluded entirely and may not be reduced below 30% of the total number of securities included in such offering, except for in connection with an initial public offering, in which case the underwriters may exclude these holders entirely.

Expenses of Registration Rights

We generally will pay all expenses, other than underwriting discounts, selling commissions and stock transfer taxes incurred in connection with each of the registrations described above, including the fees and disbursements, not to exceed $50,000, of one counsel for the selling holders.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Expiration of Registration Rights

The registration rights described above will expire, with respect to any particular holder of these rights, on the earliest to occur of (a) the closing of a deemed liquidation event, as defined in our restated certificate of incorporation, (b) at such time that all of the holder's registrable securities can be sold without limitation in any three-month period without registration in compliance with Rule 144 or a similar exemption under the Securities Act and (c) seven years following the completion of this offering.

Anti-Takeover Provisions

The provisions of Delaware General Corporation Law, or DGCL, our restated certificate of incorporation and our restated bylaws, as we expect they will be in effect upon the completion of this offering, could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Restated Certificate of Incorporation and Restated Bylaw Provisions

Our restated certificate of incorporation and our restated bylaws, as we expect they will be in effect upon the completion of this offering, include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- *Board of Directors Vacancies.* Our restated certificate of incorporation and restated bylaws will authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- *Classified Board.* Our restated certificate of incorporation and restated bylaws will provide that our board of directors is classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors. See the section entitled “Management—Board Composition.”
- *Stockholder Action; Special Meetings of Stockholders.* Our restated certificate of incorporation will provide that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws will provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.
- *Advance Notice Requirements for Stockholder Proposals and Director Nominations.* Our restated bylaws will provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also will specify certain requirements regarding the form and content of a stockholder’s notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of our company.
- *No Cumulative Voting.* The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation’s certificate of incorporation provides otherwise. Our restated certificate of incorporation and restated bylaws will not provide for cumulative voting.
- *Directors Removed Only for Cause.* Our restated certificate of incorporation will provide that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.
- *Amendment of Charter Provisions.* Any amendment of the above expected provisions in our restated certificate of incorporation would require approval by holders of at least two-thirds of our outstanding common stock.

- *Issuance of Undesignated Preferred Stock.* Our board of directors has the authority, without further action by the stockholders, to issue up to shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by merger, tender offer, proxy contest or other means.
- *Choice of Forum.* Our restated certificate of incorporation will provide that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be . The transfer agent's address is .

The Nasdaq Global Select Market Listing

We intend to apply to have our common stock approved for listing on the Nasdaq Global Select Market under the symbol "ARQT."

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding options and warrants, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon the completion of this offering, we will have a total of shares of our common stock outstanding, assuming (i) the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of shares of our common stock and (ii) the issuance of shares of common stock in this offering. Of these outstanding shares, all of the shares of common stock sold in this offering will be freely tradable, except that any shares purchased in this offering by our affiliates, as that term is defined in Rule 144 under the Securities Act, can only be sold in compliance with the Rule 144 limitations described below or in compliance with the lock-up agreements.

The remaining outstanding shares of our common stock will be deemed “restricted securities” as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which rules are summarized below. In addition, substantially all of our security holders have, or will have, entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below.

Lock-Up/Market Standoff Agreements

All of our directors and officers and substantially all of our security holders are, or will be, subject to lock-up agreements or market standoff provisions that prohibit them from offering for sale, selling, contracting to sell, granting any option for the sale of, transferring or otherwise disposing of any shares of our common stock, options or warrants to acquire shares of our common stock or any security or instrument related to our common stock, or entering into any swap, hedge or other arrangement that transfers any of the economic consequences of ownership of our common stock, for a period of 180 days following the date of this prospectus without the prior written consent of Goldman Sachs & Co. LLC and Cowen and Company, LLC, subject to certain exceptions. Goldman Sachs & Co. LLC and Cowen and Company, LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, release all or any portion of the securities subject to lock-up agreements. See the section entitled “Underwriting.”

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the three months preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up and market standoff agreements described above, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average reported weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding three months to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701 and are subject to the lock-up and market standoff agreements described above.

Form S-8 Registration Statement

In connection with this offering, we intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of our common stock subject to outstanding options and the shares of our common stock reserved for issuance under our stock plans. We expect to file this registration statement as soon as permitted under the Securities Act. However, the shares registered on Form S-8 may be subject to the volume limitations and the manner of sale, notice and public information requirements of Rule 144 and will not be eligible for resale until expiration of the lock-up and market standoff agreements to which they are subject.

Registration Rights

We have granted demand, piggyback and Form S-3 registration rights to certain of our stockholders to sell our common stock. Registration of the sale of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. For a further description of these rights, see the section entitled “Description of Capital Stock—Registration Rights.”

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following summary describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the alternative minimum tax or Medicare Contribution tax on net investment income and does not deal with state or local taxes, U.S. federal gift and estate tax laws, except to the limited extent provided below, or any non-U.S. tax consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances.

Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Internal Revenue Code of 1986, as amended, or the Code, such as:

- insurance companies, banks and other financial institutions;
- tax-exempt organizations (including private foundations) and tax-qualified retirement plans;
- foreign governments and international organizations;
- broker-dealers and traders in securities;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons required for U.S. federal income tax purposes to conform the timing of income accruals to their financial statements under Section 451(b) of the Code;
- persons that own, or are deemed to own, more than 5% of our common stock;
- “controlled foreign corporations,” “passive foreign investment companies” and corporations that accumulate earnings to avoid U.S. federal income tax;
- persons that hold our common stock as part of a “straddle,” “hedge,” “conversion transaction,” “synthetic security” or integrated investment or other risk reduction strategy;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); and
- partnerships and other pass-through entities, and investors in such pass-through entities (regardless of their places of organization or formation).

Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them.

Furthermore, the discussion below is based upon the provisions of the Code, and U.S. Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, possibly retroactively, and are subject to differing interpretations which could result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions or that the IRS will not take a contrary position regarding the tax consequences described herein, or that any such contrary position would not be sustained by a court.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK IN LIGHT OF THEIR PARTICULAR SITUATIONS, AS

WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE LAWS OF ANY OTHER TAXING JURISDICTION, INCLUDING ANY STATE, LOCAL OR NON-U.S. TAX CONSEQUENCES OR ANY U.S. FEDERAL NON-INCOME TAX CONSEQUENCES, AND THE POSSIBLE APPLICATION OF TAX TREATIES. IN ADDITION, SIGNIFICANT CHANGES IN U.S. FEDERAL TAX LAWS WERE RECENTLY ENACTED.

For the purposes of this discussion, a “Non-U.S. Holder” is a beneficial owner of common stock that is not a U.S. Holder or a partnership for U.S. federal income tax purposes. A “U.S. Holder” means a beneficial owner of our common stock that is, for U.S. federal income tax purposes, (a) an individual citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If you are an individual non-U.S. citizen, you may, in some cases, be deemed to be a resident alien (as opposed to a nonresident alien) by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. Generally, for this purpose, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year, are counted.

Resident aliens are generally subject to U.S. federal income tax as if they were U.S. citizens. Individuals who are uncertain of their status as resident or nonresident aliens for U.S. federal income tax purposes are urged to consult their own tax advisors regarding the U.S. federal income tax consequences of the ownership or disposition of our common stock.

Distributions

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. If we do make distributions on our common stock, however, such distributions made to a Non-U.S. Holder of our common stock will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a Non-U.S. Holder’s adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock as described below under the section entitled “—Gain on Disposition of Our Common Stock.”

Any distribution on our common stock that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the holder’s conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder’s country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder’s entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the

holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to the applicable withholding agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

See also the sections below entitled "—Backup Withholding and Information Reporting" and "—Foreign Accounts" for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

Gain on Disposition of Our Common Stock

Subject to the discussions below under the sections entitled "—Backup Withholding and Information Reporting" and "—Foreign Accounts," a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of the holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that the holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a "United States real property holding corporation" within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or the holder's holding period in the common stock.

If you are a Non-U.S. Holder, gain described in (a) will be subject to tax on the net gain derived from the sale at the regular graduated U.S. federal income tax rates applicable to U.S. persons. If you are a corporate Non-U.S. Holder, gain described in (a) above may also be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by certain U.S. source capital losses (even though you are not considered a resident of the United States), provided you have timely filed U.S. federal income tax returns with respect to such losses. With respect to (c) above, in general, we would be a United States real property holding corporation if U.S. real property interests as defined in the Code and the U.S. Treasury Regulations comprised (by fair market value) at least half of our worldwide real property interests plus our other assets used or held for use in a trade or business. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation. However, there can be no assurance that we will not become a United States real property holding corporation in the future. Even if we were to be treated as a U.S. real property holding

corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock would not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly or constructively, no more than five percent of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will qualify as regularly traded on an established securities market.

U.S. Federal Estate Tax

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and, therefore, will be included in the taxable estate of a nonresident alien decedent, unless an applicable estate tax treaty between the United States and the decedent's country of residence provides otherwise. The terms "resident" and "nonresident" are defined differently for U.S. federal estate tax purposes than for U.S. federal income tax purposes. Investors are urged to consult their own tax advisors regarding the U.S. federal estate tax consequences of the ownership or disposition of our common stock.

Backup Withholding and Information Reporting

Generally, we or an applicable withholding agent must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, or otherwise establishes an exemption, provided that the applicable withholding agent does not have actual knowledge or reason to know the holder is a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., unless the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, or otherwise meets documentary evidence requirements for establishing non-U.S. person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. If backup withholding is applied to you, you should consult with your own tax advisor to determine whether you have overpaid your U.S. federal income tax, and whether you are able to obtain a tax refund or credit of the overpaid amount.

Foreign Accounts

In addition, U.S. federal withholding taxes may apply under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments, including dividends paid to non-U.S. financial institutions

and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution agrees to undertake certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. The 30% federal withholding tax described in this paragraph cannot be reduced under an income tax treaty with the United States. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally would also apply to payments of gross proceeds from the sale or other disposition of common stock. Under recently proposed Treasury Regulations, however, no withholding will apply with respect to payments of gross proceeds. The preamble to the proposed Treasury Regulations specify that taxpayers are permitted to rely on such proposed Treasury Regulations pending finalization.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS SUCH AS ESTATE AND GIFT TAX, AND THE POSSIBLE APPLICATION OF TAX TREATIES.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC and Cowen and Company, LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	
Cowen and Company, LLC	
Guggenheim Securities, LLC	
Cantor Fitzgerald & Co.	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days from the date of this prospectus. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by the company. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

Paid by the Company

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

We estimate that our total out of pocket expenses for this offering, excluding the underwriting discounts and commissions, will be approximately $. We have also agreed to reimburse the underwriters for up to $ of expenses related to the review of this offering by the Financial Industry Regulatory Authority, Inc. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

As part of the Series C convertible preferred stock financing in October 2019, Broad Street Principal Investments, L.L.C, or BSPI, an affiliate of Goldman Sachs & Co. LLC, purchased 343,949 shares of our Series C convertible preferred stock. These shares and the shares of our common stock received by BSPI upon conversion of the Series C convertible preferred stock are subject to the 180-day lock-up restrictions applicable to existing stockholders and described herein. These shares and the shares of our common stock received by BSPI upon conversion of the Series C convertible preferred stock are considered underwriting compensation and are therefore also subject to certain lock-up restrictions pursuant to FINRA Rule 5110(g). Pursuant to FINRA Rule 5110(g), BSPI has agreed that

such shares of Series C convertible preferred stock and the shares of our common stock received by BSPI upon conversion of the Series C convertible preferred stock will not be sold during this offering, or sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such shares of Series C convertible preferred stock or common stock by any person for a period of 180 days immediately following the date of effectiveness of the registration statement of which this prospectus is a part or commencement of sales of common stock in this offering, except as permitted by FINRA Rule 5110(g)(2).

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We have agreed that, subject to certain limited exceptions, we will not (i) offer, sell, contract to sell, pledge, lend, grant any option to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, or file with or confidentially submit to the SEC a registration statement under the Securities Act relating to, any of our securities that are substantially similar to our shares of common stock, including but not limited to any options or warrants to purchase shares of common stock or any securities that are convertible into or exchangeable for, or that represent the right to receive, shares of common stock or any such substantially similar securities, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition, confidential submission or filing or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our shares of common stock or any such other securities (in either case, regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of the representatives for a period through and including the date that is 180 days after the date of this prospectus.

Our directors, executive officers and substantially all of our stockholders have entered into lock-up agreements with the underwriters, pursuant to which each of these persons or entities, subject to certain limited exceptions, for a period through and including the date that is 180 days after the date of this prospectus, agree that they will not, and shall not cause or direct any of their respective affiliates to, (i) offer, sell, contract to sell, pledge, grant any option to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock, or any options or warrants to purchase any shares of common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of common stock, whether now owned or hereafter acquired, owned directly by each such person or entity (including holding as a custodian) or with respect to which such person or entity has beneficial ownership within the rules and regulations of the SEC, (ii) engage in any hedging or other transaction or arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition (whether by such person or entity or someone other than such person or entity), or transfer of any of the economic consequences of ownership, in whole or in part, directly or indirectly, of the securities owned by such person or entity, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of common stock or other securities, in cash or otherwise, or (iii) otherwise publicly announce any intention to engage in or cause any action or activity described in clause (i) above or transaction or arrangement described in clause (ii) above.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of the our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We intend to apply to list our common stock on the Nasdaq Global Select Market under the symbol “ARQT”.

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments

and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to Prospective Investors in European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or each, a Relative Member State, an offer to the public of shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive:

- To any legal entity which is a qualified investor as defined in the Prospectus Directive;
- To fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the Representatives for any such offer; or
- In any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer or shares of our common stock shall result in a requirement for the publication by us or any of the underwriters of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to public” in relation to shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and shares of our common stock to be offered so as to enable an investor to decide to purchase shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (as amended), including by Directive 2010/73/EU and includes any relevant implementing measure in the Relevant Member State.

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Notice to Prospective Investors in United Kingdom

In the United Kingdom, this prospectus is only addressed to and directed as qualified investors who are (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order); or (ii) high net worth entities and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Any investment or investment activity to which this prospectus relates is available only to relevant persons and will only be engaged with relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Notice to Prospective Investors in Switzerland

The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

Notice to Prospective Investors in Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or Companies (Winding Up and Miscellaneous Provisions) Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or Securities and Futures Ordinance, or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be

accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or

to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Notice to Prospective Investors in Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728—1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed Investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Fenwick & West LLP, San Francisco, California. Certain legal matters relating to the offering will be passed upon for the underwriters by Latham & Watkins LLP, Menlo Park, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2017 and 2018, and for each of the two years in the period ended December 31, 2018, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to the financial statements). We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits filed therewith. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete, please see the copy of the contract or document that has been filed for the complete contents of that contract or document. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

We currently do not file periodic reports with the SEC. Upon the completion of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Securities Exchange Act of 1934, as amended. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We also maintain a website at www.arcutis.com. Upon completion of this offering, you may access these materials at our website free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained in, or that can be accessed through, our website is not a part of, and is not incorporated into, this prospectus.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

INDEX TO FINANCIAL STATEMENTS

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Arcutis, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Arcutis, Inc. (the Company) as of December 31, 2018 and 2017, the related statements of operations, statements of convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits include performing procedures to assess the risks of material misstatement on the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2019.

/s/ Ernst & Young LLP

Los Angeles, California
September 9, 2019

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Balance Sheets
(In thousands, except share and per share data)

	December 31, 2017	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,418	$ 39,394
Marketable securities	—	11,546
Prepaid expenses and other current assets	401	158
Total current assets	3,819	51,098
Total assets	$ 3,819	$ 51,098
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 537	$ 1,801
Accrued liabilities	155	872
Total current liabilities	692	2,673
Convertible preferred stock liability	966	—
Other long-term liabilities	—	160
Total liabilities	1,658	2,833
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.0001 par value; 10,805,000 and 32,536,270 shares authorized at December 31, 2017 and 2018, respectively; 7,484,209 and 32,536,267 shares issued and outstanding at December 31, 2017 and 2018, respectively; aggregate liquidation preference of $7,484 and $71,800 at December 31, 2017 and 2018, respectively	7,154	72,252
Stockholders' deficit:		
Common stock, $0.0001 par value; 17,850,000 and 44,000,000 shares authorized at December 31, 2017 and 2018, respectively; 3,394,739 and 5,233,154 shares issued at December 31, 2017 and 2018, respectively; 1,845,890 and 3,116,903 shares outstanding at December 31, 2017 and 2018, respectively	—	—
Additional paid-in capital	28	289
Accumulated deficit	(5,021)	(24,276)
Total stockholders' deficit	(4,993)	(23,987)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 3,819	$ 51,098

The accompanying notes are an integral part of these financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

**Statements of Operations
(In thousands, except share and per share data)**

	Year Ended December 31,	
	2017	2018
Operating expenses:		
Research and development	$ 3,411	$ 17,940
General and administrative	695	1,795
Total operating expenses	4,106	19,735
Loss from operations	(4,106)	(19,735)
Other income (expense), net	(872)	480
Net loss	$ (4,978)	$ (19,255)
Net loss per share, basic and diluted	$ (3.58)	$ (7.76)
Weighted-average shares used in computing net loss per share, basic and diluted	1,391,097	2,480,246
Pro forma net loss per share, basic and diluted (unaudited)		$
Weighted-average shares used in computing pro forma net loss per share, basic and diluted (unaudited)		

The accompanying notes are an integral part of these financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

**Statements of Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share data)**

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance—December 31, 2016	—	$ —	1,018,422	$ —	$ 1	$ (43)	$ (42)
Issuance of Series A convertible preferred stock, net of issuance costs of $115 and convertible preferred stock liability of $219	7,184,209	6,850	—	—	—	—	—
Issuance of Series A convertible preferred stock upon conversion of convertible promissory notes	300,000	304	—	—	—	—	—
Vesting of founder shares subject to repurchase	—	—	827,468	—	—	—	—
Stock-based compensation expense	—	—	—	—	27	—	27
Net loss	—	—	—	—	—	(4,978)	(4,978)
Balance—December 31, 2017	7,484,209	7,154	1,845,890	—	28	(5,021)	(4,993)
Issuance of Series A convertible preferred stock, net of issuance costs of $21 and value of convertible preferred stock liability of $891	6,315,791	7,186	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $88	17,767,150	54,912	—	—	—	—	—
Issuance of Series B convertible preferred stock in connection with license agreement	969,117	3,000	—	—	—	—	—
Issuance of common stock upon the exercise of stock options	—	—	228,529	—	43	—	43
Vesting of founder shares subject to repurchase	—	—	721,382	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	321,102	—	67	—	67
Stock-based compensation expense	—	—	—	—	151	—	151
Net loss	—	—	—	—	—	(19,255)	(19,255)
Balance—December 31, 2018	32,536,267	$72,252	3,116,903	$ —	$ 289	$ (24,276)	$ (23,987)

The accompanying notes are an integral part of these financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2017	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(4,978)	$(19,255)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net amortization/accretion on marketable securities	—	(14)
Stock-based compensation	27	151
Issuance of convertible preferred stock in connection with license agreement	—	3,000
Change in fair value of convertible preferred stock liability	747	(75)
Change in fair value of derivative liability	150	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(401)	243
Accounts payable	537	1,264
Accrued liabilities	143	601
Net cash used in operating activities	(3,775)	(14,085)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	—	(11,532)
Net cash used in investing activities	—	(11,532)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	—	386
Proceeds from issuance of Series A convertible preferred stock, net of issuance costs	7,069	6,295
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	54,912
Proceeds from issuance of convertible promissory note payable	50	—
Net cash provided by financing activities	7,119	61,593
Net increase in cash and cash equivalents	3,344	35,976
Cash and cash equivalents at beginning of period	74	3,418
Cash and cash equivalents at end of period	$ 3,418	$ 39,394
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Conversion of convertible promissory notes payable into convertible preferred stock	$ 304	$ —
Convertible preferred stock liability recorded in connection with convertible preferred stock	$ 219	$ —
Convertible preferred stock issued in connection with license agreement	$ —	$ 3,000
Reclassification of convertible preferred stock liability to Series A convertible preferred stock	$ —	$ 891

The accompanying notes are an integral part of these financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

1. Organization and Description of Business

Arcutis, Inc., or the Company, is a clinical-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. The Company's current portfolio is comprised of topical treatments with significant promise in addressing immune-mediated dermatological diseases and conditions, or immuno-dermatology. The Company's strategy is to advance treatments that leverage validated biological targets in dermatology while delivering a clinical profile that addresses major shortcomings of existing therapies in its targeted indications. The Company believes this strategy uniquely positions it to rapidly advance its goal of bridging the treatment innovation gap in dermatology, all while maximizing our probability of technical success.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $24.3 million as of December 31, 2018. The Company had cash, cash equivalents and marketable securities of $50.9 million as of December 31, 2018. The Company has historically financed its operations primarily through the sale of its convertible preferred stock. Management expects operating losses to continue for the foreseeable future.

The Company does not believe that its existing capital resources will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of its financial statements. The Company believes that this raises substantial doubt about its ability to continue as a going concern. As a result, the Company will be required to raise additional capital. However, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to significantly reduce its operating expenses. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company's ability to achieve its intended business objectives and have an adverse effect on its results of operations and future prospects. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates such estimates and assumptions for continued reasonableness. In particular, management makes estimates with respect to accruals for

research and development activities, fair value of common stock and convertible preferred stock, fair value of convertible preferred stock liability, stock-based compensation expense and income taxes. Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation. Actual results could differ from those estimates.

Segments

To date, the Company has viewed its financial information on an aggregate basis for the purposes of evaluating financial performance and allocating the Company's resources. Accordingly, the Company has determined that it operates in one segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of money market funds, commercial paper, and government securities. The Company did not have any cash equivalents as of December 31, 2017.

Marketable Securities

Marketable securities consist of investment grade short to intermediate-term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase are classified as current based on their availability for use in current operations. The Company did not have any marketable securities as of December 31, 2017.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on marketable securities are included in other income (expense), net. To date no such other than temporary declines in fair value have occurred or have been recorded. The cost of investments sold is based on the specific-identification method. There were no realized gains or losses on investments for the year ended December 31, 2018. Interest on marketable securities is included in other income (expense), net.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the balance sheets.

Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 3 *Fair Value Measurements*, include cash equivalents, accounts payable and accrued liabilities. The carrying amount of cash equivalents, accounts payable and accrued liabilities approximate their fair values due to their short maturities.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active;

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Preclinical and Clinical Accruals and Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical studies, clinical trials and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. For the years ended December 31, 2017 and 2018, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Convertible Preferred Stock

The Company classifies convertible preferred stock outside of stockholders' deficit on its balance sheets as the requirements of triggering a deemed liquidation event, as defined within its amended and restated certificate of incorporation, are not entirely within the Company's control. In the event of such a deemed liquidation event, the proceeds from the event are distributed in accordance with the liquidation preferences (see Note 8), provided that the holders of convertible preferred stock have not

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

converted their shares into common stock. The Company records the issuance of convertible preferred stock at the issuance price less related issuance costs. The Company has not adjusted the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty as to whether or when a deemed liquidation event may occur.

Convertible Preferred Stock Liability

The freestanding rights of Series A convertible preferred stockholders to purchase additional shares of the Company's Series A convertible preferred stock in a subsequent closing, contingent upon approval by the board of directors, at a fixed price per share, are accounted for as a liability at fair value as the shares underlying the right contain contingent redemption features outside the control of the Company. The liability was subject to re-measurement at each balance sheet date until settlement, with changes in fair value recognized as a component of other income (expense), net in the statements of operations. In March 2018, the convertible preferred stock liability was settled upon the issuance of the second tranche of Series A convertible preferred stock and the fair value of the liability was reclassified to the Series A convertible preferred stock.

Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, license fees, stock-based compensation expense, materials, supplies, and the cost of services provided by outside contractors. All costs associated with research and development are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or services are rendered. Such payments are evaluated for current or long-term classification based on when they will be realized.

The Company has entered into and may continue to enter into, license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date none of the Company's license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expense when paid or becomes payable, provided there is no alternative future use of the rights in other research and development projects.

Stock-Based Compensation

The Company accounts for share-based payments at fair value. The fair value of stock options is measured using the Black-Scholes option-pricing model. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for such awards is the date of grant and the expense is recognized on a straight-line basis, over the expected vesting period. For share-based awards that vest subject to a performance condition, the Company will recognize compensation cost for awards if and when the Company concludes that it is probable that the awards with a performance condition will be achieved on an accelerated attribution method. The Company accounts for forfeitures as they occur.

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the

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PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. The Company records a valuation allowance to reduce deferred tax assets to an amount for which realization is more likely than not. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes the tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

Unaudited Pro Forma Net Loss Per Share

The unaudited pro forma basic and diluted net loss per share has been computed to give effect to the conversion of all outstanding convertible preferred stock into shares of common stock upon either (i) the closing of a firm-commitment underwritten public offering at a per share price of at least $4.6434, resulting in at least $50.0 million in net proceeds, or Qualified Public Offering, or (ii) by vote or written consent of the holders of a majority of the then outstanding shares of Series A and B convertible preferred stock. The unaudited pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the initial public offering, or IPO, of the Company's common stock. The unaudited pro forma net loss per share for the year ended December 31, 2018 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock into shares of common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates if later. The net loss has also been adjusted to reverse the gains or losses resulting from the remeasurement of the convertible preferred stock liability.

Comprehensive Loss

Comprehensive loss consists of net loss and other comprehensive income or loss. As of the latest balance sheet presented, the Company has not had any transactions that are required to be reported in comprehensive loss other than the net loss incurred from operations.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02, *Leases* (Topic 842) (ASC 842), which establishes a comprehensive new lease accounting model. The new standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The new standard is effective for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, an update which provides another transition method, the prospective transition method, which allows entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted the standard on January 1, 2019. As of December 31, 2018, the Company had not entered into any leases within the scope of the standard.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* or ASU No. 2016-13*.* This update will require the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Financial institutions and other organizations will now include forward-looking information in the determination of their credit loss estimates. Many of the loss estimation techniques applied today will still be permitted, although the inputs to those techniques will change to reflect the full amount of expected credit losses. In addition, this update amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. This update clarified the effective date of ASU No. 2016-13 for nonpublic business entities to fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021. Early application of ASU No. 2016-13 will be permitted for all organizations for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact that the standard will have on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* or ASU No. 2018-13, which removes, modifies, and adds various disclosure requirements on fair value measurements in Topic 820. ASU No. 2018-13 is effective for fiscal years and interim periods within

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

those fiscal years beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this update. An entity is permitted to early adopt any removed or modified disclosures upon issuance of this update and delay adoption of the additional disclosures until their effective date. The Company does not expect a significant impact from adopting this update on its financial statements.

Recently Adopted Accounting Pronouncements

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments—Overall* (Topic 825)*—Recognition and Measurement of Financial Assets and Financial Liabilities*, which amends the guidance in U.S. GAAP on the classification and measurement of financial instruments. The new standard revises an entity's accounting related to (i) the classification and measurement of investments in equity securities and (ii) the presentation of certain fair value changes for financial liabilities measured at fair value. The new standard also amends certain disclosure requirements associated with the fair value of financial instruments. The new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted for all entities whose financial statements have not yet been issued or have not been made available for issuance with respect to certain changes made to ASC 825. The Company early adopted this guidance as of January 1, 2018. Refer to Note 3 for more information and disclosures related to this amended guidance.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation* (Topic 718)*—Improvements to Employee Share Based Payment Accounting* as part of the FASB simplification initiative. The new standard provides for changes to accounting for stock compensation including (i) excess tax benefits and tax deficiencies related to share based payment awards will be recognized as income tax expense or benefit in the reporting period in which they occur; (ii) excess tax benefits will be classified as an operating activity in the statement of cash flows; (iii) the option to elect to estimate forfeitures or account for them when they occur; and (iv) increase of the tax withholding requirements threshold to qualify for equity classification. The standard is effective for fiscal years beginning after December 15, 2017 and interim periods within fiscal years beginning after December 15, 2018. The Company early adopted this guidance as of January 1, 2017 and the impact of its adoption on the Company's financial statements was not material. The Company elected a policy to account for forfeitures as they occur.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*. This standard is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of Topic 718, (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The standard is effective for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606. The Company early adopted this standard on January 1, 2018 and the impact of its adoption on the Company's financial statements was not material.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

3. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred stock liability	$ —	$ —	$ 966	$ 966
Total liabilities	$ —	$ —	$ 966	$ 966

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$20,509	$ —	$ —	$20,509
Commercial paper	—	15,431	—	15,431
Government securities	15,000	—	—	15,000
Total assets	$35,509	$15,431	$ —	$50,940

(1) This balance includes cash requirements settled on a nightly basis.

There were no transfers between Levels 1, 2 or 3 for any of the periods presented. The Company did not have any financial assets measured at fair value as of December 31, 2017 or liabilities measured as of December 31, 2018.

The following table summarizes the estimated value of the Company's cash, cash equivalents and marketable securities and the gross unrealized holding gains and losses (in thousands):

	December 31, 2018			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Commercial paper	3,885	—	—	3,885
Money market funds(1)	20,509	—	—	20,509
Government securities	15,000	—	—	15,000
Total cash and cash equivalents	39,394	—	—	39,394
Marketable securities:				
Commercial paper	11,546	—	—	11,546
Total marketable securities	$ 11,546	$ —	$ —	$ 11,546

(1) This balance includes cash requirements settled on a nightly basis.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

The following table summarizes the change in the fair value of the convertible preferred stock liability for the years ended December 31, 2017 and 2018 (in thousands):

	Year Ended December 31,	
	2017	2018
Beginning balance	$ —	$ 966
Fair value at issuance	219	—
Loss (gain) from changes in fair value	747	(75)
Recognition of fair value upon issuance of convertible preferred stock	—	(891)
Ending balance	$966	$ —

The fair value of the Company's convertible preferred stock liability is based on significant inputs not observed in the market, and thus represents a Level 3 measurement. The Company estimates the fair value of this liability using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31,	
	2017	2018
Expected term (in years)	1.0 – 4.0	4.1
Expected volatility	63.2 – 69.8%	65.4%
Risk-free interest rate	1.42 – 2.15%	2.53%
Dividend yield	—%	—%

The following table summarizes the change in the fair value of the derivative liability for the year ended December 31, 2017 (in thousands):

	Year Ended December 31, 2017
Beginning balance	$ —
Loss from changes in fair value	150
Reclassification to convertible preferred stock upon conversion of the convertible promissory notes	(150)
Ending balance	$ —

The fair value of the Company's derivative liability is based on significant inputs not observed in the market, and thus represents a Level 3 measurement. Refer to Note 5 for further discussion on the derivative liability and related valuation.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2017	2018
Prepaid clinical trial costs	$221	$ 40
Other prepaid expenses and current assets	180	118
Total prepaid expenses and other current assets	$401	$158

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2017	2018
Accrued compensation	$142	$455
Clinical trial accruals	—	250
Early exercise liability, current	—	116
Accrued expenses and other current liabilities	13	51
Total accrued liabilities	$155	$872

5. Convertible Promissory Notes Payable to Related Parties

In August 2016, the Company entered into a Convertible Promissory Note Purchase Agreement, or the Purchase Agreement, with a founder and an investor, or the Holders, who are related parties. Under the terms of the Purchase Agreement, the Company could issue up to $1.0 million of convertible promissory notes, or the Notes, with a one-year maturity. The Notes bear interest at a rate of 6.0% per annum, compounded annually, and payable at maturity. In the event of an equity financing with minimum proceeds in an amount approved by the Company's board of directors, the outstanding balance of the Notes is automatically converted into shares of stock issued in the equity financing based on a conversion price equal to 50% of the issuance price paid by investors in said financing.

The Company issued Notes in the amount of $100,000 in August 2016 and $50,000 in March 2017. The redemption of the Notes upon an equity financing was determined to be a contingent redemption feature that was not clearly and closely related to the Notes and was bifurcated and recognized as a derivative liability on the balance sheet. The fair value of the derivative liability was estimated to be insignificant on the issuance dates of August 2016 and March 2017.

In April 2017, the Company issued 7,184,209 shares of Series A convertible preferred stock to investors at $1.00 per share for net proceeds of $7.1 million. At the time of conversion, the value of the derivative liability was determined to be $150,000 and the increase in fair value was recorded as other operating expense. Accordingly, the outstanding principal balance of $150,000 of the Notes was automatically converted into 300,000 shares of Series A convertible preferred stock and the derivative liability was settled. The carrying value of the Notes of $154,000 and the derivative liability of $150,000 were reclassified to Series A convertible preferred stock.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

6. License Agreements

AstraZeneca License Agreement

In July 2018, the Company entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca AB, or AstraZeneca, granting the Company a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, commercialize and otherwise exploit products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, the AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. Under this agreement, the Company has sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at its expense, and it shall use commercially reasonable efforts to develop, obtain and maintain regulatory approvals for, and commercialize the AZ-Licensed Products in the Dermatology Field in each of the United States, Italy, Spain, Germany, the United Kingdom, France, China, and Japan.

The Company paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 969,117 shares of Series B preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. In addition, the Company has agreed to make cash payments to AstraZeneca of up to an aggregate of $14.5 million upon the achievement of specified clinical development and regulatory approval milestones with respect to the AZ-Licensed Products and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products the Company commercializes under the AstraZeneca License Agreement, it will pay AstraZeneca a low to high single-digit percentage royalty rate on the Company's, its affiliates' and its sublicensees' net sales of such AZ-Licensed Products, subject to specified reductions, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. The first milestone payment of $2.0 million became due in July 2019 upon the achievement of positive Phase 2 data and was subsequently paid in August 2019.

For the year ended December 31, 2018, the Company recorded research and development expense of $4.0 million related to the upfront fee payment and the issuance of Series B convertible preferred stock.

Hengrui Exclusive Option and License Agreement

In January 2018, the Company entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, whereby Hengrui granted the Company an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, and the European Union (including for clarity the United Kingdom). The initial option period under the agreement extended to June 2019, and was subsequently amended to extend until January 2020. The Company made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui License Agreement which was recorded as research and development expense. If the Company exercises its exclusive option, it will pay Hengrui an additional $1.5 million

option exercise cash payment. In addition, if exercised, the Company has agreed to make cash payments of up to an aggregate of $20.5 million upon achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $200 million in sales-based milestones based on certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products the Company commercializes under the Hengrui License Agreement, it will pay tiered royalties to Hengrui on net sales of each licensed product by the Company, or its affiliates, or its sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the later of (1) expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, the Company is obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income it receives from sublicensees of its rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

7. Commitments and Contingencies

Operating Lease

As of December 31, 2018, the Company had not entered into any long-term operating lease agreements. The Company entered into a lease agreement in January 2019 as described in Note 13.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by California corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

8. Convertible Preferred Stock and Stockholders' Deficit

Convertible preferred stock as of December 31, 2017 consisted of the following (in thousands, except share amounts):

Convertible Preferred Stock	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Liquidation Preference
Series A	10,805,000	7,484,209	$ 7,154	$ 7,484
Total	10,805,000	7,484,209	$ 7,154	$ 7,484

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

Convertible preferred stock as of December 31, 2018 consisted of the following (in thousands, except share amounts):

Convertible Preferred Stock	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Liquidation Preference
Series A	13,800,000	13,800,000	$ 14,340	$ 13,800
Series B	18,736,270	18,736,267	57,912	58,000
Total	32,536,270	32,536,267	$ 72,252	$ 71,800

In April 2017, the Company entered into a Stock Purchase Agreement with investors, some of which were related parties, to issue 10,800,000 shares of Series A convertible preferred stock at $1.00 per share in three tranches. The first tranche, consisting of 7,184,209 shares for net proceeds of $7.1 million, was completed upon execution of the agreement. Additionally, the Company issued 300,000 shares of Series A convertible preferred stock as a result of the conversion of convertible promissory notes with an outstanding principal amount of $154,000 and the settlement of the derivative liability of $150,000 (see Note 5).

The Series A investors were also granted freestanding rights to participate in additional tranches to raise a minimum of $3.3 million, upon election by the board of directors including at least one of the Series A directors, by purchasing 3,315,791 shares of Series A convertible preferred stock at $1.00 per share in two tranches, provided such election occurs prior to April 2019. The two tranches consisted of 1,657,889 shares and 1,657,902 shares, respectively. The Company concluded that the investors' rights to purchase Series A convertible preferred shares met the definition of a freestanding financial instrument, as they were legally detachable and separately exercisable from the Series A convertible preferred stock, or the Series A Convertible Preferred Stock Liability. As the Series A Convertible Preferred Stock Liability was redeemable at the election of holders of the then-outstanding shares, it represented a liability to be accounted for at fair value and remeasured at each reporting period.

Changes in fair value are recognized as a gain or loss in other income (expense), net in the statement of operations. On the closing of the first tranche in April 2017, the Company recorded the initial fair value of the Series A Convertible Preferred Stock Liability of $219,000 for the second and the third tranche participating rights by reducing the carrying value of Series A convertible preferred stock.

In March 2018, the Company completed the second tranche closing and issued 6,315,791 shares of Series A convertible preferred stock to the investors at $1.00 per share for net proceeds of $6.3 million. The Series A Convertible Preferred Stock Liability was remeasured to fair value just prior to settlement and the carrying value of the liability of $891,000 was reclassified to Series A convertible preferred stock. Concurrently with the closing of the second tranche, the Company amended the Series A convertible preferred stock purchase agreement to merge the second and third tranches and increased the maximum number of shares to be issued in the second tranche to 6,315,791 shares. For the years ended December 31, 2017 and 2018, the Company recorded a net loss of $747,000 and a gain of $75,000, respectively, in the statements of operations for the change in fair value of the liability.

In September 2018, the Company issued 18,736,267 shares of Series B convertible preferred stock at $3.0956 per share for total proceeds of $57.9 million, some of which were to related parties.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

Significant provisions of the Company's convertible preferred stock are as follows:

Conversion Rights

Each share of convertible preferred stock is convertible into shares of common stock determined by dividing the original issuance price by the conversion price. The conversion price is equal to the original issuance price, which is $1.00 for Series A convertible preferred stock and $3.0956 for Series B convertible preferred stock. All series of convertible preferred stock will convert into shares of common stock on a one-to-one basis. The conversion price will be adjusted for stock splits, distributions, dividends, noncash distributions, share purchase rights, and capital reorganizations. In addition, the conversion price for each series of convertible preferred stock will be reduced upon the issuance or sale by the Company of common shares or instruments convertible or exercisable into common shares, for consideration or with an exercise price that is less than the conversion price applicable to such series. Such reduction may result in recognition by the Company of a deemed dividend to convertible preferred stockholders, if the resulting conversion price is less than the fair value per share of common stock as of the date convertible preferred stock was issued.

Conversion can occur at any time at the option of each holder. In addition, all shares of convertible preferred stock will convert automatically upon (a) the closing of a Qualified Public Offering or (b) by vote or written consent of the holders of a majority of the then outstanding shares of Series A and B convertible preferred stock.

Liquidation Rights

In the event of any liquidation (including a change in control), dissolution, or winding up of the Company, either voluntary or involuntary, each stockholder of Series A and B convertible preferred stock will be entitled to receive, prior and in preference to any distribution of any assets or surplus funds to the holders of common stock, an amount per share equal to the applicable original issue price of $1.00 and $3.0956 per share for the Series A and B convertible preferred stock, respectively, in addition to all declared but unpaid dividends. If the full amount is not available for distribution the entire assets and funds legally available will be distributed ratably among the holders of Series B convertible preferred stock first, then if any amount is left preferential payments will be made to Series A convertible preferred stockholders. After the distributions described above have been paid in full, the remaining assets of the Company will be distributed among the common stockholders and convertible preferred stockholders pro rata based on the number of shares held by each holder on an as-converted to common stock on a one-to-one basis.

Voting Rights

Each share of Series A and B convertible preferred stock has the right to one vote for each share of common stock into which such convertible preferred stock could be converted and with respect to such vote, such holder will have full voting rights and powers equal to holders of common stock. With regard to the election of directors: (i) the holders of a majority of the Series B convertible preferred stock, voting as a separate class, are entitled to elect two directors; (ii) the holders of a majority of the Series A convertible preferred stock, voting as a separate class, are entitled to elect two directors; (iii) the holders of a majority of the common stock, voting as a

separate class, are entitled to elect two directors; and (iv) the holders of a majority of the shares of common stock and convertible preferred stock, exclusively and voting together as a single class, are entitled to elect the remaining directors. There is a total of seven members on the Company's Board of Directors.

Dividend Rights

Each stockholder of Series A and B convertible preferred stock is entitled to receive dividends when, as and if declared by the board of directors at the rate that is higher of (i) 6% of the original issue price per annum or (ii) pro rata dividend rate on an as-converted basis together with other convertible preferred stock and common stock. Dividends are noncumulative, and no cash dividends have been declared to date.

Redemption Rights

The Series A and B convertible preferred stocks are not currently redeemable. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, the convertible preferred stock is contingently redeemable.

Common Stock

The holders of the Company's common stock have one vote for each share of common stock. Common stockholders are entitled to dividends when, as, and if declared by the Board of Directors, subject to the prior rights of the convertible preferred stockholders. The holders have no preemptive or other subscription rights and there are no redemption or sinking fund provisions with respect to such shares. As of December 31, 2018, no dividends had been declared by the Board of Directors.

The Company reserved the following shares of common stock for issuance as follows:

	December 31,	
	2017	2018
Convertible preferred stock outstanding	7,484,209	32,536,267
Options issued and outstanding	946,316	782,481
Options available for future grant	6,732,794	5,058,214
Total common stock reserved	15,163,319	38,376,962

9. Stock-Based Compensation

In April 2017, the Company adopted the 2017 Equity Incentive Plan, or the 2017 Plan. The 2017 Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company under terms and provisions established by the board of directors. Under the terms of the 2017 Plan, options may be granted at an exercise price not less than fair market value. The Company generally grants stock-based awards with service conditions. Options granted typically vest over a four-year period but may be granted with different vesting terms.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

As of December 31, 2018, the Company had 5,058,214 shares available for future grant under the 2017 Plan.

Stock Option Activity

The following summarizes option activity under the 2017 Plan (in thousands, except share amounts):

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2016	—	$ —	—	$ —
Granted	946,316	$ 0.18		
Exercised	—			
Balance—December 31, 2017	946,316	$ 0.18	9.40	$ 360
Granted	1,674,580	$ 0.32		
Exercised	(1,838,415)	$ 0.21		
Balance—December 31, 2018	782,481	$ 0.41	9.56	$ 334
Exercisable—December 31, 2018	477,481(1)	$ 0.29	9.46	$ 263

(1) Options exercisable includes early exercisable options.

The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock, as determined by the board of directors, as of December 31, 2018.

No options were exercised for the year ended December 31, 2017. The intrinsic value of options exercised for the year ended December 31, 2018 was $678,000.

The total grant-date fair value of the options vested during 2017 and 2018 was $25,000 and $130,000, respectively. The weighted-average grant-date fair value of employee options granted during the years ended December 31, 2017 and 2018 was $0.17 and $0.46 per share, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense recognized was as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Research and development	$ 8	$ 44
General and administrative	19	107
Total stock-based compensation expense	$ 27	$151

As of December 31, 2018, there was $759,000 of total unrecognized compensation cost related to unvested options that are expected to vest. The cost is expected to be recognized over a weighted-average period of 3.3 years.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

In determining the fair value of the stock options granted, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

Fair value of common stock—Given the absence of a public trading market, the Company's board of directors with input from management considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to: (i) third-party valuations of the Company's common stock; (ii) the Company's stage of development; (iii) the status of research and development efforts; (iv) the rights, preferences and privileges of the Company's convertible preferred stock relative to those of the Company's common stock; (v) the Company's operating results and financial condition, including the Company's levels of available capital resources; and (vi) equity market conditions affecting comparable public companies; (vii) general U.S. market conditions; and (viii) the lack of marketability of the Company's common stock.

Expected Term—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding. The Company used the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term.

Expected Volatility—Since the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Dividend Yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of stock option awards granted was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2017	2018
Expected term (in years)	6.0	5.9 – 6.1
Expected volatility	84.4 – 84.5%	68.2 – 72.4%
Risk-free interest rate	1.9%	2.7 – 2.9%
Dividend yield	—%	—%

Early Exercise of Employee Options

The terms of the 2017 Plan permit certain option holders to exercise options before their options are vested, subject to certain limitations. Upon early exercise, the awards become subject to a

restricted stock agreement. The shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. Such shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $276,000 as a liability from the early exercise in the accompanying balance sheet. As of December 31, 2018, there were $116,000 recorded in accrued liabilities and $160,000 recorded in other long-term liabilities related to shares that were subject to repurchase.

Founder Awards

In August 2016, the Company issued 2,376,317 shares of restricted common stock to founders of which 2,206,579 shares vest under a service condition and 169,738 shares vest under a performance condition. The shares were issued under the terms of the respective restricted stock purchase agreements, or the Stock Purchase Agreement, and unvested shares are subject to repurchase by the Company at the original purchase price per share upon the holder's termination of his relationship with the Company. The restricted shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. One-fourth of the 2,206,579 shares of restricted common stock were vested on the first-anniversary date and the remaining 1,654,934 shares will vest on a monthly basis thereafter. In July 2018, performance conditions prescribed by the Stock Purchase Agreement were met and 169,738 shares of the restricted common stock were fully vested. During the years ended December 31, 2017 and 2018, 827,468 shares and 551,644 shares of restricted common stock were vested, respectively. As of December 31, 2018, 827,467 shares of restricted stock are unvested.

10. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2017 and December 31, 2018. The Company has incurred net operating losses only in the United States since its inception. The Company has not reflected any benefit of such net operating loss carryforwards in the financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

Reconciliation of income tax computed at federal statutory rates to the reported provision for income taxes is as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Tax provision at U.S. statutory rate	$(1,692)	$(4,043)
State income taxes, net of federal benefit	(224)	(1,224)
Tax credits	(68)	(265)
Change in valuation allowance	885	4,418
Uncertain tax positions	186	911
Permanent differences	124	219
Fair value adjustment	305	(16)
Change in federal statutory rate	484	—
Provision for income tax	$ —	$ —

Significant components of the Company's deferred income taxes at December 31, 2017 and 2018 are shown below (in thousands):

	December 31,	
	2017	2018
Deferred tax assets:		
Accruals and reserves	$ 36	$ 117
Net operating loss	739	3,606
Research and development credits and other credits	98	458
Intangibles	26	1,132
Stock-based compensation	1	6
Gross deferred tax assets	900	5,319
Less valuation allowance	(900)	(5,319)
Total deferred tax assets	$ —	$ —

On December 22, 2017, the U.S. government enacted comprehensive tax legislation, commonly known as the Tax Cuts and Jobs Act of 2017, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. The Tax Act contains broad and complex changes to corporate taxation, including in part, reduction of the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously considered permanently reinvested, and creates new taxes on certain foreign sourced earnings. In December 2017, the SEC issued Staff Accounting Bulletin No. 118, or SAB 118, which provides guidance on accounting for the income tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting relating to the Tax Act under Accounting Standards Codification Topic 740, *Income Taxes*, or ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Tax Act for which the accounting under ASC 740 is complete. The Company has completed its evaluation and there is no impact on its December 31, 2018 financial statements. As a result of the rate reduction, the Company has reduced the deferred tax asset balance as of December 31, 2017 by $484,000. Due to the Company's full valuation allowance position, the Company has also reduced the valuation allowance by the same amount.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $885,000 and $4.4 million during the years ended December 31, 2017 and 2018, respectively.

The Company has net operating loss carryforwards for federal and state income tax purposes of approximately $17.2 million and $18.1 million, respectively, as of December 31, 2018. Of the federal net operating losses, $3.5 million originated before the 2018 tax year and will expire beginning in 2036. Under the Tax Act, the remaining $13.6 million of net operating losses generated after December 31, 2017 will be carried forward indefinitely with utilization limited to 80% of taxable income. The state net operating loss carryforwards, if not utilized, will expire beginning in 2036.

As of December 31, 2018, the Company also had federal and California research and development tax credit carryforwards of $751,000 and $261,000, respectively. The federal research and development tax credit carryforwards will begin to expire in 2037. The California research and development tax credit carryforwards are available indefinitely.

Federal and California tax laws impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 and 383. The Company has not completed a formal study to determine the limitations on their tax attributes due to change in ownership and may have limitations on the utilization of net operating loss carryforwards, credit carryforwards, or other tax attributes due to ownership changes.

Uncertain Tax Benefits

No liability related to uncertain tax positions is recorded on the financial statements related to uncertain tax positions. It is the Company's policy to include penalties and interest expense related to income taxes as a component of other income (expense), net, as necessary.

The following table summarizes the activity related to the unrecognized benefits (in thousands):

	Year Ended December 31,	
	2017	2018
Beginning balance	$ —	$ 441
Increases related to tax positions taken during a prior year	—	—
Increases related to tax positions taken during the current year	441	1,800
Ending balance	$441	$2,241

The reversal of the uncertain tax benefits would not affect the effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months.

Income tax returns are filed in the U.S. and California. The Company is not currently under audit by the Internal Revenue Service or similar state or local authorities. The years 2016 and forward remain open to examination by the domestic taxing jurisdictions to which the Company is subject. Net operating losses generated on a tax return basis by the Company for 2016 and forward remain open to examination by the domestic taxing jurisdictions.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS, INC.

Notes to Financial Statements

11. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of December 31,	
	2017	2018
Convertible preferred stock on an as-converted basis	7,484,209	32,536,267
Stock options to purchase common stock	946,316	782,481
Early exercised options subject to future vesting	—	1,288,784
Restricted stock subject to future vesting	1,548,849	827,467
Total	9,979,374	35,434,999

12. Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of unaudited pro forma basic and diluted net loss per share during the year ended December 31, 2018 (in thousands, except share and per share data):

	Year Ended December 31, 2018 (unaudited)
Numerator	
Net loss	$ (19,255)
Change in fair value of convertible preferred stock liability	(75)
Net loss used in computing pro forma net loss per share, basic and diluted	$ (19,330)
Denominator	
Weighted-average shares of common stock used in computing net loss per share	2,480,246
Pro forma adjustment to reflect assumed conversion of convertible preferred stock	
Weighted-average shares of common stock used in computing pro forma net loss per share, basic and diluted	
Pro forma net loss per share, basic and diluted	$

13. Subsequent Events

Subsequent events have been evaluated through September 9, 2019, which is the date that the financial statements were available to be issued.

Lease

In January 2019, the Company entered into a lease agreement for office space in Westlake Village, California, that expires in July 2021. The total future lease payments are $465,000 for the 30 month term of the lease.

Hawkeye Collaboration Agreement

In June 2019, the Company entered into a collaboration agreement, or Hawkeye Agreement, with Hawkeye Therapeutics, Inc., or Hawkeye, a related party with common ownership, to collaborate on

the research and development of one or more new applications of roflumilast. The Hawkeye Agreement grants Hawkeye an exclusive license to certain intellectual property developed under the agreement as it relates to the applications. Under the terms of the Hawkeye Agreement, the Company is required to perform certain research and development activities that are fully funded by Hawkeye.

Contemporaneously with the execution of the Hawkeye Agreement, the Company entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye's common stock at $0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye. The shares are subject to a right to repurchase by Hawkeye. The right to repurchase lapses at a rate of one-sixth each month, vesting over the six-month term of the Hawkeye Agreement. In the event that Hawkeye issues shares of Series A preferred stock with proceeds over $5.0 million, Hawkeye is required to issue to the Company a number of fully-paid fully-vested shares of common stock determined by dividing (i) $2,000,000 by (ii) an amount equal to the cash price per share for Series A preferred stock.

AstraZeneca License Agreement

In July 2019, the Company achieved its first regulatory milestone of positive Phase 2 data for an AZ-Licensed Product under the AstraZeneca License Agreement resulting in a $2.0 million cash milestone payment to AstraZeneca, which the Company paid in August 2019.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Condensed Balance Sheets
(Unaudited)
(In thousands, except share and per share data)**

	December 31, 2018 (Note 2)	September 30, 2019	Pro forma Stockholders' Equity as of September 30, 2019
ASSETS			
Current assets:			
Cash and cash equivalents	$ 39,394	$ 23,177	
Marketable securities	11,546	2,000	
Prepaid expenses and other current assets	158	2,594	
Total current assets	51,098	27,771	
Property, plant, and equipment	—	185	
Operating lease right-of-use asset	—	300	
Other assets	—	47	
Total assets	$ 51,098	$ 28,303	
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY			
Current liabilities:			
Accounts payable	$ 1,801	$ 3,159	
Accrued liabilities	872	5,267	
Operating lease liability	—	173	
Total current liabilities	2,673	8,599	
Operating lease liability, noncurrent	—	175	
Other long-term liabilities	160	227	
Total liabilities	2,833	9,001	
Commitments and contingencies (Note 7)			
Convertible preferred stock, $0.0001 par value; 32,536,270 shares authorized at December 31, 2018 and September 30, 2019; 32,536,267 shares issued and outstanding at December 31, 2018 and September 30, 2019; actual, aggregate liquidation preference of $71,800 at December 31, 2018 and September 30, 2019; no shares issued and outstanding as of September 30, 2019, pro forma	72,252	72,252	$ —
Stockholders' (deficit) equity:			
Common stock, $0.0001 par value; 44,000,000 shares authorized at December 31, 2018 and September 30, 2019; 5,233,154 and 5,735,065 shares issued at December 31, 2018 and September 30, 2019, respectively; 3,116,903 and 3,957,764 shares outstanding at December 31, 2018 and September 30, 2019, respectively; shares issued and outstanding as of September 30, 2019, pro forma	—	—	
Additional paid-in capital	289	754	
Accumulated other comprehensive income	—	—	
Accumulated deficit	(24,276)	(53,704)	
Total stockholders' (deficit) equity	(23,987)	(52,950)	$
Total liabilities, convertible preferred stock and stockholders' deficit	$ 51,098	$ 28,303	

The accompanying notes are an integral part of these unaudited condensed financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Condensed Statements of Operations
(Unaudited)
(In thousands, except share and per share data)**

	Nine Months Ended September 30,	
	2018	2019
Operating expenses:		
Research and development	$ 12,593	$ 25,765
General and administrative	1,189	4,373
Total operating expenses	13,782	30,138
Loss from operations	(13,782)	(30,138)
Other income, net	128	710
Net loss	$ (13,654)	$ (29,428)
Net loss per share, basic and diluted	$ (5.92)	$ (8.30)
Weighted-average shares used in computing net loss per share, basic and diluted	2,305,932	3,547,292
Pro forma net loss per share, basic and diluted		$
Weighted-average shares used in computing pro forma net loss per share, basic and diluted		

The accompanying notes are an integral part of these unaudited condensed financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Condensed Statements of Comprehensive Loss
(Unaudited)
(In thousands)**

	Nine Months Ended September 30,	
	2018	2019
Net loss	$(13,654)	$(29,428)
Other comprehensive income:		
Unrealized gain on marketable securities, net of tax	—	—
Comprehensive loss	$(13,654)	$(29,428)

The accompanying notes are an integral part of these unaudited condensed financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit
(Unaudited)
(In thousands, except share data)**

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance—December 31, 2017	7,484,209	$ 7,154	1,845,890	$ —	$ 28	$ —	$ (5,021)	$ (4,993)
Issuance of Series A convertible preferred stock, net of issuance costs of $21 and value of convertible preferred stock liability of $891	6,315,791	7,186	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $88	17,767,150	54,912	—	—	—	—	—	—
Issuance of common stock upon the exercise of stock options	969,117	3,000	228,529	—	43	—	—	43
Vesting of founder shares subject to repurchase	—	—	583,471	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	189,322	—	38	—	—	38
Stock-based compensation	—	—	—	—	95	—	—	95
Net loss	—	—	—	—	—	—	(13,654)	(13,654)
Balance—September 30, 2018	32,536,267	$72,252	2,847,212	$ —	$ 204	$ —	$ (18,675)	$ (18,471)

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PURSUANT TO 17 C.F.R. SECTION 200.83

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance—December 31, 2018	32,536,267	$72,252	3,116,903	$ —	$ 289	$ —	$ (24,276)	$ (23,987)
Issuance of common stock upon the exercise of stock options	—	—	31,782	—	9	—	—	9
Vesting of founder shares subject to repurchase	—	—	413,734	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	395,345	—	87	—	—	87
Stock-based compensation	—	—	—	—	369	—	—	369
Other comprehensive income	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(29,428)	(29,428)
Balance—September 30, 2019	32,536,267	$72,252	3,957,764	$ —	$ 754	$ —	$ (53,704)	$ (52,950)

The accompanying notes are an integral part of these unaudited condensed financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Condensed Statements of Cash Flows
(Unaudited)
(In thousands)**

	Nine Months Ended September 30,	
	2018	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(13,654)	$(29,428)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	44
Non-cash operating lease expense	—	91
Accretion of discounts and amortization of premiums on marketable securities	—	(357)
Issuance of convertible preferred shares in connection with license agreement	3,000	—
Stock-based compensation	95	369
Change in fair value of convertible preferred stock liability	(75)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(39)	(1,408)
Other assets	—	(47)
Accounts payable	2,146	889
Accrued liabilities	280	3,851
Operating lease liabilities	—	(43)
Net cash used in operating activities	(8,247)	(26,039)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	—	(22,897)
Proceeds from maturities of marketable securities	—	32,800
Purchases of property and equipment	—	(229)
Net cash used in investing activities	—	9,674
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	386	256
Proceeds from issuance of convertible preferred stock, net of issuance costs	61,207	—
Payment of financing costs	—	(108)
Net cash provided by financing activities	61,593	148
Net increase (decrease) in cash and cash equivalents	53,346	(16,217)
Cash and cash equivalents at beginning of period	3,418	39,394
Cash and cash equivalents at end of period	$ 56,764	$ 23,177
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Reclassification of convertible preferred stock liability to Series A convertible preferred stock	$ 891	$ —
Deferred financing costs included in accounts payable and accrued liabilities	$ —	$ 920
Right-of-use asset obtained in exchange for lease liability	$ —	$ 391

The accompanying notes are an integral part of these unaudited condensed financial statements.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

1. Organization and Description of Business

Arcutis Biotherapeutics, Inc., or the Company, is a clinical-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. In October 2019, the Company changed its name from Arcutis, Inc. to Arcutis Biotherapeutics, Inc. The Company's current portfolio is comprised of topical treatments with significant promise in addressing immune-mediated dermatological diseases and conditions, or immuno-dermatology. The Company's strategy is to advance treatments that leverage validated biological targets in dermatology while delivering a clinical profile that addresses major shortcomings of existing therapies in its targeted indications. The Company believes this strategy uniquely positions it to rapidly advance its goal of bridging the treatment innovation gap in dermatology, all while maximizing its probability of technical success.

Liquidity Risks

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $53.7 million as of September 30, 2019. The Company had cash and cash equivalents and marketable securities of $25.2 million as of September 30, 2019. Additionally, in October 2019, the Company received $94.5 million in gross cash proceeds from the sale of its Series C convertible preferred stock. See Note 12. The Company has historically financed its operations primarily through the sale of its convertible preferred stock. Management expects operating losses to continue for the foreseeable future.

The Company believes that its existing capital resources, including the cash proceeds received from the issuance of Series C convertible preferred stock, will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of its financial statements. The Company will be required to raise additional capital to fund future operations. However, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to significantly reduce its operating expenses. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company's ability to achieve its intended business objectives and have an adverse effect on its results of operations and future prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates such estimates and assumptions for continued reasonableness. In particular, management makes estimates with respect to accruals for research and development activities, fair value of common stock and convertible preferred stock, fair value of convertible preferred stock liability, stock-based compensation expense and income taxes.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation. Actual results could differ from those estimates.

Unaudited Interim Condensed Financial Statements

The interim condensed balance sheet as of September 30, 2019, and the interim condensed statements of operations, comprehensive loss, changes in convertible preferred stock and stockholders' deficit and cash flows for the nine months ended September 30, 2018 and 2019 are unaudited. These unaudited interim condensed financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair statement of the Company's financial information. The financial data and the other financial information disclosed in these notes to the condensed financial statements related to the nine-month periods are also unaudited. The condensed results of operations for the nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2018 included herein was derived from the audited financial statements as of that date. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Therefore, these interim condensed financial statements should be read in conjunction with the Company's audited financial statements included elsewhere in this prospectus.

Unaudited Pro Forma Information

In contemplation of the Company's planned initial public offering, or IPO, the unaudited pro forma stockholders' equity in the condensed balance sheets reflects shares of the Company's common stock outstanding as of September 30, 2019 and assumes the conversion of all outstanding shares of convertible preferred stock into common stock upon either (i) the closing of a firm-commitment underwritten public offering at a per share price of at least $4.6434, resulting in at least $50.0 million in net proceeds, or Qualified Public Offering, or (ii) by vote or written consent of the holders of a majority of the then outstanding shares of Series A and B convertible preferred stock. The shares of common stock issuable and the proceeds expected to be received in the IPO are excluded from such pro forma information.

Marketable Securities

Marketable securities consist of investment grade short to intermediate-term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase are classified as current based on their availability for use in current operations.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

Realized gains and losses and declines in fair value judged to be other than temporary, if any, on marketable securities are included in other income (expense), net. To date no such other than temporary declines in fair value have occurred or have been recorded. The cost of investments sold is based on the specific-identification method. There were no realized gains or losses on investments for the nine months ended September 30, 2018 and 2019. Interest on marketable securities is included in other income, net.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the balance sheets.

Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 3 *Fair Value Measurements*, include cash equivalents, accounts payable and accrued liabilities. The carrying amount of cash equivalents, accounts payable and accrued liabilities approximate their fair values due to their short maturities.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active;

Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Leases

The Company leases a facility with a non-cancelable lease term of 30 months. The term of the lease includes a renewal option at the election of the Company to extend the lease for an additional term. The renewal option has not been considered in the determination of the right-of-use, or ROU, asset or lease liability as the Company did not consider it reasonably certain it would exercise this option.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

The Company determines if an arrangement is or contains a lease at inception. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The classification of the Company's leases as operating or finance leases along with the initial measurement and recognition of the associated ROU assets and lease liabilities is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. The Company's uses its incremental borrowing rate, based on the information available at commencement date, to determine the present value of lease payments when its leases do not provide an implicit rate. The Company uses the implicit rate when readily determinable. The ROU asset is based on the measurement of the lease liability, includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The Company's lease agreement includes lease and non-lease components and the Company has elected to not separate such components. Further, the Company elected the short-term lease exception policy, permitting it to not apply the recognition requirements of this standard to leases with terms of 12 months or less (short-term leases) for all classes of assets.

Preclinical and Clinical Accruals and Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical studies, clinical trials and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs as of December 31, 2018 and September 30, 2019 and actual costs incurred.

Convertible Preferred Stock

The Company classifies convertible preferred stock outside of stockholders' deficit on its balance sheets as the requirements of triggering a deemed liquidation event, as defined within its amended and restated certificate of incorporation, are not entirely within the Company's control. In the event of such a deemed liquidation event, the proceeds from the event are distributed in accordance with the liquidation preferences (see Note 8), provided that the holders of convertible preferred stock have not converted their shares into common stock. The Company records the issuance of convertible preferred stock at the issuance price less related issuance costs. The Company has not adjusted the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty as to whether or when a deemed liquidation event may occur.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

Convertible Preferred Stock Liability

The freestanding rights of Series A convertible preferred stockholders to purchase additional shares of the Company's Series A convertible preferred stock in a subsequent closing, contingent upon approval by the board of directors, at a fixed price per share, are accounted for as a liability at fair value as the shares underlying the right contain contingent redemption features outside the control of the Company. The liability was subject to re-measurement at each balance sheet date until settlement, with changes in fair value recognized as a component of other income, net in the statement of operations and comprehensive loss. In March 2018, the convertible preferred stock liability was settled upon the issuance of the second tranche of Series A convertible preferred stock and the fair value of the liability was reclassified to the Series A convertible preferred stock.

Variable Interest Entities

The Company reviews agreements it enters into with third-party entities, pursuant to which the Company may have a variable interest in the entity, in order to determine if the entity is a variable interest entity, or VIE. If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that entity. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (i) the power to direct the economically significant activities of the entity and (ii) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If the Company determines it is the primary beneficiary of a VIE, it consolidates that VIE into the Company's financial statements. The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation or deconsolidation event.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

Unaudited Pro Forma Net Loss Per Share

The unaudited pro forma information has been provided to the conversion of all outstanding convertible preferred stock into shares of common stock. The unaudited pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the IPO of the Company's common stock. The unaudited pro forma net loss per share for the year ended September 30, 2019 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock into shares of common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates if later.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02, *Leases* (Topic 842), which establishes a comprehensive new lease accounting model. The new standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The new standard is effective for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, an update which provides another transition method, the prospective transition method, which allows entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company early adopted the standard on January 1, 2019. The adoption of the standard did not have a material impact on the Company's condensed financial statements as the Company did not have any outstanding leases as of the adoption date. Refer to Note 7 for more information and disclosures related to this amended guidance.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

3. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$20,509	$ —	$ —	$20,509
Commercial paper	—	15,431	—	15,431
Government securities	15,000	—	—	15,000
Total assets	$35,509	$15,431	$ —	$50,940

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

	September 30, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$20,177	$ —	$ —	$20,177
Government securities	5,000	—	—	5,000
Total assets	$25,177	$ —	$ —	$25,177

(1) This balance includes cash requirements settled on a nightly basis.

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Commercial paper and government securities are valued taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

The following tables summarize the estimated value of the Company's cash, cash equivalents and marketable securities and the gross unrealized holding gains and losses (in thousands):

	December 31, 2018			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Commercial paper	3,885	—	—	3,885
Money market funds(1)	20,509	—	—	20,509
Government securities	15,000	—	—	15,000
Total cash and cash equivalents	39,394	—	—	39,394
Marketable securities:				
Commercial paper	11,546	—	—	11,546
Total marketable securities	$ 11,546	$ —	$ —	$ 11,546

(1) This balance includes cash requirements settled on a nightly basis.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

	September 30, 2019			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds(1)	20,177	—	—	20,177
Government securities	3,000	—	—	3,000
Total cash and cash equivalents	23,177	—	—	23,177
Marketable securities:				
Government securities	2,000	—	—	2,000
Total marketable securities	$ 25,177	$ —	$ —	$ 25,177

(1) This balance includes cash requirements settled on a nightly basis.

The following table summarizes the change in the fair value of the convertible preferred stock liability for the nine months ended September 30, 2018 (in thousands):

	September 30, 2018
Beginning balance	$ 966
Gain from changes in fair value	(75)
Recognition of fair value upon issuance of convertible preferred stock	(891)
Ending balance	$ —

The fair value of the Company's convertible preferred stock liability is based on significant inputs not observed in the market, and thus represents a Level 3 measurement. The Company estimated the fair value of this liability using the Black-Scholes option pricing model with an expected term of 4.1 years, volatility of 65.4% and risk-free interest rate of 2.53% during the nine months ended September 30, 2018.

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2018	September 30, 2019
Prepaid clinical trial costs	$ 40	$ 1,278
Deferred financing costs	—	1,028
Other prepaid expenses and current assets	118	288
Total prepaid expenses and other current assets	$ 158	$ 2,594

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2018	September 30, 2019
Clinical trial accruals	$ 250	$ 3,384
Accrued compensation	455	1,093
Early exercise liability, current	116	209
Accrued expenses and other current liabilities	51	581
Total accrued liabilities	$ 872	$ 5,267

5. License Agreements

AstraZeneca License Agreement

In July 2018, the Company entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca AB, or AstraZeneca, granting the Company a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, and commercialize and otherwise exploit products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. Under the AstraZeneca License Agreement, the Company has sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at its expense, and it shall use commercially reasonable efforts to develop, obtain and maintain regulatory approvals for, and commercialize the AZ-Licensed Products in the Dermatology Field in each of the United States, Italy, Spain, Germany, the United Kingdom, France, China, and Japan.

The Company paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 969,117 shares of Series B Preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. In addition, the Company has agreed to make cash payments to AstraZeneca of up to an aggregate of $14.5 million upon the achievement of specified clinical development and regulatory approval milestones with respect to the AZ-Licensed Products and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products the Company commercializes under the agreement, it will pay AstraZeneca a low to high single-digit percentage royalty rate on the Company's, its affiliates' and sublicensees' net sales of such AZ-Licensed Products, subject to specified reductions, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. The first milestone cash payment of $2.0 million became due in July 2019 upon the achievement of positive Phase 2 data for any AZ-Licensed Product and was subsequently paid in August 2019. This payment was recorded in research and development expense.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

Hengrui Exclusive Option and License Agreement

In January 2018, the Company entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, whereby Hengrui granted the Company an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, and the European Union (including for clarity the United Kingdom). The initial option period under the agreement extended to June 2019, and was subsequently amended to extend until January 2020. The Company made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui License Agreement which was recorded as research and development expense. If the Company exercises its exclusive option, it will pay Hengrui an additional $1.5 million option exercise cash payment. In addition, if exercised, the Company has agreed to make cash payments of up to an aggregate of $20.5 million upon achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $200.0 million in sales-based milestones based on certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products the Company commercializes under the Hengrui License Agreement, it will pay tiered royalties to Hengrui on net sales of each licensed product by the Company, or its affiliates, or its sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the later of (1) expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, the Company is obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income it receives from sublicensees of its rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

6. Related Party Transactions

Hawkeye Collaboration Agreement

In June 2019, the Company entered into a collaboration agreement, or the Hawkeye Agreement, with Hawkeye Therapeutics, Inc., or Hawkeye, a related party with common ownership, to collaborate on the research and development of one or more new applications of roflumilast. The Hawkeye Agreement grants Hawkeye an exclusive license to certain intellectual property developed under the agreement as it relates to the applications. Under the terms of the Hawkeye Agreement, the Company is required to perform certain research and development activities that are fully funded by Hawkeye.

Contemporaneously with the execution of the Hawkeye Agreement, the Company entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye's common stock at $0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye. The shares are subject to a right to repurchase by Hawkeye. The right to repurchase lapses at a rate of one-sixth each month, vesting over the six-month term of the Hawkeye Agreement. In the event that Hawkeye issues shares of Series A preferred stock with proceeds over $5.0 million, Hawkeye is required to issue to the Company a number of fully-paid fully-vested shares of common stock determined by dividing (i) $2.0 million by (ii) an amount equal to the cash price per share for Series A preferred stock. Other than the potential issuance of this common stock, there are no upfront payments, milestones or royalties pursuant to the Hawkeye Agreement. The Company determined that Hawkeye is a variable interest entity for which consolidation is not required as it is not the primary beneficiary.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

7. Commitments and Contingencies

Operating Lease

The Company leases one facility in Westlake Village, California under an operating lease that commenced in February 2019 and has a non-cancelable lease term of 30 months, subject to fixed escalation increases. The lease contains an option to extend for an additional term, however, the Company is not reasonably certain to exercise the option for the lease.

The minimum annual rental payments of the Company's operating lease liability as of September 30, 2019 are as follows (in thousands):

	Amounts
2019 (remaining three months)	$ 47
2020	192
2021	132
Total minimum lease payments	371
Less: Amounts representing interest	23
Present value of future minimum lease payments	$ 348
Current portion operating lease liability	173
Operating lease liability, noncurrent	175
Total operating lease liability	$ 348

Straight-line rent expense recognized for operating leases was $109,000 for the nine months ended September 30, 2019. There were no variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the period of nine months ended September 30, 2019.

The following information represents supplemental disclosure for the condensed statement of cash flows related to the Company's operating lease (in thousands):

	September 30, 2019
Cash flows from operating activities	
Cash paid for amounts included in the measurement of lease liabilities	$ 94

The following summarizes additional information related to the operating lease:

	September 30, 2019
Weighted-average remaining lease term (in years)	1.9
Weighted-average discount rate	7.0%

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

8. Convertible Preferred Stock

Convertible preferred stock as of December 31, 2018 and September 30, 2019 consisted of the following (in thousands, except share amounts):

Convertible Preferred Stock	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Liquidation Preference
Series A	13,800,000	13,800,000	$ 14,340	$ 13,800
Series B	18,736,270	18,736,267	57,912	58,000
Total	32,536,270	32,536,267	$ 72,252	$ 71,800

In October 2019, the Company sold an aggregate of 16,251,628 shares of its Series C convertible preferred stock at a purchase price of $5.8148 per share for an aggregate gross purchase price of approximately $94.5 million. See Note 12.

9. Stock-Based Compensation

In April 2017, the Company adopted the 2017 Equity Incentive Plan, or the 2017 Plan. The 2017 Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company under terms and provisions established by the board of directors. Under the terms of the 2017 Plan, options may be granted at an exercise price not less than fair market value. The Company generally grants stock-based awards with service conditions. Options granted typically vest over a four-year period but may be granted with different vesting terms.

As of September 30, 2019, the Company had 2,191,014 shares available for future grant under the 2017 Plan. In October 2019, in connection with the issuance of the Series C convertible preferred stock, the Company effected an increase to the shares available for future grant under the 2017 Plan of 2,823,831 additional shares. See Note 12.

Stock Option Activity

The following summarizes option activity under the 2017 Plan (in thousands, except share amounts):

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2018	782,481	$ 0.41	9.56	$ 334
Granted	2,930,950	$ 0.84		
Exercised	(501,911)	$ 0.51		
Fortified	(63,750)	$ 0.29		
Balance—September 30, 2019	3,147,770	$ 0.80	9.35	$ 133
Exercisable—September 30, 2019	1,981,626(1)	$ 0.80	9.31	$ 83

(1) Options exercisable includes early exercisable options.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock, as determined by the board of directors, as of September 30, 2019.

The intrinsic value of options exercised for the nine months ended September 30, 2019 was $166,000.

For the nine months ended September 30, 2018 and 2019, the total grant-date fair value of the options vested was $81,000 and $203,000, respectively, and the estimated weighted-average grant-date fair value of employee options granted was $0.45 and $0.54 per share, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense recognized was as follows (in thousands):

	Nine Months Ended September 30,	
	2018	2019
Research and development	$ 25	$ 146
General and administrative	70	223
Total stock-based compensation expense	$ 95	$ 369

As of September 30, 2019, there was $1.9 million of total unrecognized compensation cost related to unvested options that are expected to vest. The cost is expected to be recognized over a weighted-average period of 3.5 years.

In determining the fair value of the stock options granted, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

Fair value of common stock—Given the absence of a public trading market, the Company's board of directors with input from management considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to: (i) third-party valuations of the Company's common stock; (ii) the Company's stage of development; (iii) the status of research and development efforts; (iv) the rights, preferences and privileges of the Company's convertible preferred stock relative to those of the Company's common stock; (v) the Company's operating results and financial condition, including the Company's levels of available capital resources; (vi) equity market conditions affecting comparable public companies; (vii) general U.S. market conditions; and (viii) the lack of marketability of the Company's common stock.

Expected Term—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding. The Company used the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term.

Expected Volatility—Since the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average historical

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Dividend Yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of stock option awards granted was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2018	2019
Expected term (in years)	6.0 – 6.1	5.9 – 6.6
Expected volatility	70.3 – 72.4%	68.6 – 70.4%
Risk-free interest rate	2.7 – 2.9%	2.0 – 2.6%
Dividends yield	—%	—%

Early Exercise of Employee Options

The terms of the 2017 Plan permit certain option holders to exercise options before their options are vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement. The shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. Such shares are not deemed to be issued for accounting purposes until those related shares vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $276,000 and $436,000 as a liability as of December 31, 2018 and September 30, 2019, respectively, from the early exercise in the accompanying condensed balance sheet. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. As of December 31, 2018 and September 30, 2019, there were $116,000 and $209,000, respectively, recorded in accrued liabilities and $160,000 and $227,000 recorded in other long-term liabilities as of December 31, 2018 and September 30, 2019, respectively, related to shares that were subject to repurchase.

Founder Awards

In August 2016, the Company issued 2,376,317 shares of restricted common stock to founders of which 2,206,579 shares vest under a service condition and 169,738 shares vest under a performance condition. The shares were issued under the terms of the respective restricted stock purchase

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

agreements, or the Stock Purchase Agreement, and unvested shares are subject to repurchase by the Company at the original purchase price per share upon the holder's termination of his relationship with the Company. Such restricted shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. One-fourth of the 2,206,579 shares of restricted common stock were vested on the first-anniversary date and the remaining 1,654,934 shares will vest on a monthly basis thereafter. In July 2018, performance conditions prescribed by the Stock Purchase Agreement were met and 169,738 shares of the restricted common stock were fully vested. During the nine months ended September 30, 2019, 413,734 shares of restricted common stock were vested. As of September 30, 2019, 413,733 shares of restricted stock are unvested.

10. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Nine Months Ended September 30,	
	2018	2019
Convertible preferred stock on an as-converted basis	32,536,267	32,536,267
Stock options to purchase common stock	607,481	3,147,770
Early exercised options subject to future vesting	1,420,563	1,363,567
Restricted stock subject to future vesting	965,379	413,733
Total	35,529,690	37,461,337

11. Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of unaudited pro forma basic and diluted net loss per share during the nine months ended September 30, 2019 (in thousands, except share and per share data):

	Year Ended September 30, 2019 (unaudited)
Numerator	
Net loss used in computing pro forma net loss per share, basic and diluted	$ (29,428)
Denominator	
Weighted-average shares of common stock used in computing net loss per share	3,547,292
Pro forma adjustment to reflect assumed conversion of convertible preferred stock	
Weighted-average shares of common stock used in computing pro forma net loss per share, basic and diluted	
Pro forma net loss per share, basic and diluted	$

12. Subsequent Events

Subsequent events have been evaluated through November 12, 2019, which is the date that the condensed financial statements were available to be issued.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

ARCUTIS BIOTHERAPEUTICS, INC.

**Notes to Condensed Financial Statements
(unaudited)**

Series C Convertible Preferred Stock Financing

In October 2019, the Company sold an aggregate of 16,251,628 shares of its Series C convertible preferred stock at a purchase price of $5.8148 per share for an aggregate gross purchase price of approximately $94.5 million. Each share of our Series C convertible preferred stock will convert automatically into one share of our common stock upon the completion of this offering. The rights and preferences of the Series C convertible preferred stock are similar to those of the Series A and Series B convertible preferred stock, except that (i) the Original Issue Price for Series C convertible preferred stock is $5.8148 per share, (ii) the holders of the Series C convertible preferred stock have preference over the Series A and Series B convertible preferred stock in the instance of a liquidation event, and (iii) the holders of a majority of the Series C convertible preferred stock, voting as a separate class are entitled to elect one member to the Company's Board of Directors. Also in connection with the closing, the terms of a qualified public offering requiring the conversion of all shares of the Company's convertible preferred stock into common stock were changed to be net proceeds of not less than $50 million and a price of not less than $6.9777 per share, subject to appropriate adjustment for any stock dividend, stock split, combination or other similar recapitalization.

Increase in Authorized Shares of Common Stock and Preferred Stock

In October 2019, the Company effected an increase in the number of authorized shares of its common stock from 44,000,000 shares to 65,820,000 shares and an increase in the number of authorized shares of its preferred stock from 32,536,270 shares to 48,787,895 shares, of which 16,251,628 shares were designated as Series C convertible preferred stock.

Increase in Shares Reserved for Issuance under the 2017 Plan

In October 2019, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2017 Plan from 7,679,110 shares to 10,502,941 shares.

Table of Contents

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Shares

Arcutis Biotherapeutics, Inc.

Common Stock

PROSPECTUS

Goldman Sachs & Co. LLC **Cowen** **Guggenheim Securities**

Cantor

Through and including , (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by the Registrant in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Approval, or FINRA, filing fee and the Nasdaq Global Select Market listing fee:

	Amount Paid or To Be Paid
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq Global Select Market listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky, qualification fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the Delaware General Corporation Law, or DGCL, authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the DGCL are sufficiently broad to permit indemnification under certain circumstances for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

As permitted by the DGCL, the Registrant's restated certificate of incorporation to be effective in connection with the completion of this offering contains provisions that eliminate the personal liability of its directors for monetary damages for any breach of fiduciary duties as a director, except liability for the following:

- any breach of the director's duty of loyalty to the Registrant or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL (regarding unlawful dividends and stock purchases); or
- any transaction from which the director derived an improper personal benefit.

As permitted by the DGCL, the Registrant's restated bylaws to be effective in connection with the completion of this offering, provide that:

- the Registrant is required to indemnify its directors and executive officers to the fullest extent permitted by the DGCL, subject to limited exceptions;

- the Registrant may indemnify its other employees and agents as set forth in the DGCL;
- the Registrant is required to advance expenses, as incurred, to its directors and executive officers in connection with a legal proceeding to the fullest extent permitted by the DGCL, subject to limited exceptions; and
- the rights conferred in the restated bylaws are not exclusive.

Prior to the completion of this offering, the Registrant intends to enter into indemnification agreements with each of its current directors and executive officers to provide these directors and executive officers additional contractual assurances regarding the scope of the indemnification set forth in the Registrant's restated certificate of incorporation and restated bylaws and to provide additional procedural protections. There is no pending litigation or proceeding involving a director or executive officer of the Registrant for which indemnification is sought. Reference is also made to the underwriting agreement to be filed as Exhibit 1.1 to this registration statement, which provides for the indemnification of executive officers, directors and controlling persons of the Registrant against certain liabilities. The indemnification provisions in the Registrant's restated certificate of incorporation, restated bylaws and the indemnification agreements entered into or to be entered into between the Registrant and each of its directors and executive officers may be sufficiently broad to permit indemnification of the Registrant's directors and executive officers for liabilities arising under the Securities Act.

The Registrant maintains standard policies of directors' and officers' liability insurance under which coverage is provided to its directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.

The following lists set forth information regarding all securities sold or granted by the Registrant from September 1, 2016 through October 10, 2019 that were not registered under the Securities Act, and the consideration, if any, received by the Registrant for such securities:

(a) Stock Option Grants

Since September 1, 2016 and through October 10, 2019, the Registrant has granted to its employees, directors, consultants and other service providers options to purchase an aggregate of 5,551,846 shares of common stock under the 2017 Plan, with an average exercise price of $0.57 per share. The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

(b) Preferred Stock

In October 2019, the Registrant issued and sold to eleven accredited investors an aggregate of 16,251,628 shares of Series C convertible preferred stock at a purchase price of $5.8148 per share, for aggregate consideration of approximately $94.5 million. In connection with the completion of this offering, these shares of Series C convertible preferred stock will convert into 16,251,628 shares of the Registrant's common stock. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act.

In September 2018, the Registrant issued and sold to eight accredited investors an aggregate of 18,736,267 shares of Series B convertible preferred stock at a purchase price of $3.0956 per share, for

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

aggregate consideration of approximately $58.0 million. In connection with the completion of this offering, these shares of Series B convertible preferred stock will convert into 18,736,267 shares of the Registrant's common stock. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act.

In April 2017 and March 2018, the Registrant issued and sold to ten accredited investors an aggregate of 13,800,000 shares of Series A convertible preferred stock at a purchase price of $1.00 per share, for aggregate consideration of approximately $13.5 million. In connection with the completion of this offering, these shares of Series A convertible preferred stock will convert into 13,800,000 shares of the Registrant's common stock. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering, and the Registrant believes each transaction was exempt from the registration requirements of the Securities Act as stated above. All recipients of the foregoing transactions either received adequate information about the Registrant or had access, through their relationships with the Registrant, to such information. Furthermore, the Registrant affixed appropriate legends to the share certificates and instruments issued in each foregoing transaction setting forth that the securities had not been registered and the applicable restrictions on transfer.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

Exhibit Number	Description of Document
1.1*	Form of Underwriting Agreement.
3.1#	Certificate of Incorporation, as amended to date, as currently in effect.
3.2*	Form of Restated Certificate of Incorporation to be effective upon the completion of this offering.
3.3#	Bylaws, as amended to date, as currently in effect.
3.4*	Form of Restated Bylaws to be effective upon the completion of this offering.
4.1*	Form of Common Stock Certificate.
4.2†#	Amended and Restated Investors' Rights Agreement, dated October 8, 2019, by and among the Registrant and certain of its stockholders.
5.1*	Opinion of Fenwick & West LLP.
10.1*	Form of Indemnity Agreement.
10.2#	2017 Stock Incentive Plan, and forms of award agreements.
10.3*	2020 Equity Incentive Plan, to become effective on the date immediately prior to the date the registration statement is declared effective, and forms of award agreements.
10.4*	2020 Employee Stock Purchase Plan, to become effective on the date the registration statement is declared effective, and forms of award agreements.
10.5*	Offer Letter, dated , by and between the Registrant and Todd Franklin Watanabe, to become effective on the date immediately prior to the date the registration statement is declared effective.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

Exhibit Number	Description of Document
10.6*	Offer Letter, dated , by and between the Registrant and David W. Osborne, to become effective on the date immediately prior to the date the registration statement is declared effective.
10.7*	Offer Letter, dated , by and between the Registrant and Howard G. Welgus, M.D., to become effective on the date immediately prior to the date the registration statement is declared effective.
10.8#	Consulting Agreement, dated August 16, 2016, by and between Bhaskar Chaudhuri and the Registrant.
10.9*	Office Lease Agreement, dated January 31, 2019, by and between Westlake Park Place, Inc. and the Registrant.
10.10†^	License Agreement, dated July 23, 2018, by and between AstraZeneca AB and the Registrant.
10.11†^	Exclusive Option and License Agreement, dated January 4, 2018, by and between Jiangsu Hengrui Medicine Co., Ltd. and the Registrant.
10.12†^	Collaboration Agreement, dated June 28, 2019, by and between Hawkeye Therapeutics, Inc. and the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Fenwick & West LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included in the signature page to this registration statement).

* To be filed by amendment.
† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.
^ Registrant has omitted schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.
# Previously filed.

(b) Financial Statement Schedules.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

ITEM 17. UNDERTAKINGS.

The undersigned Registrant hereby undertakes to provide to the underwriters at the completion specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in

connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**CONFIDENTIAL TREATMENT REQUESTED BY ARCUTIS BIOTHERAPEUTICS, INC.
PURSUANT TO 17 C.F.R. SECTION 200.83**

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Westlake Village, State of California, on the day of .

ARCUTIS BIOTHERAPEUTICS, INC.

By: _____
Todd Franklin Watanabe
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Todd Franklin Watanabe and John W. Smither, and each of them, as his true and lawful attorneys-in-fact, proxies and agents, each with full power of substitution and resubstitution and full power to act without the other, for him in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, proxies and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, proxies and agents, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Todd Franklin Watanabe	President, Chief Executive Officer and Director (Principal Executive Officer)	
John W. Smither	Chief Financial Officer (Principal Accounting and Financial Officer)	
Bhaskar Chaudhuri, Ph.D.	Director, Chairman	
Alexander G. Asam, Ph.D	Director	
Daniel J. Estes, Ph.D.	Director	
Patrick J. Heron	Director	
Jonathan T. Silverstein, J.D.	Director	
Ricky Sun, Ph.D.	Director	

Exhibit 10.10

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED, AND HAS BEEN MARKED WITH "[***]" TO INDICATE WHERE OMISSIONS HAVE BEEN MADE

Final Execution Copy

LICENSE AGREEMENT

between

ASTRAZENECA AB

and

ARCUTIS, INC.

Dated as of July 23, 2018

TABLE OF CONTENTS

SCHEDULES

LICENSE AGREEMENT

This License Agreement (the "**Agreement**") is made and entered into effective as of July 23, 2018 (the "**Effective Date**") by and between **AstraZeneca AB**, a company incorporated in Sweden under no. 556011-7482 with offices at Pepparedsleden 1, SE-431 83 Mölndal, Sweden ("**AstraZeneca**") and **Arcutis, Inc.**, a corporation incorporated in Delaware, United States having its principal place of business at 70 Willow Road, Suite 200, Menlo Park, CA 94025 ("**Licensee**"). AstraZeneca and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, AstraZeneca owns and controls certain intellectual property rights with respect to the Licensed Compound (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein); and

WHEREAS, AstraZeneca wishes to grant a license to Licensee and Licensee wishes to take, a license under such intellectual property rights to develop and commercialize Licensed Products in the Field (as defined herein) in the Territory, in each case in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**AAA**" has the meaning set forth in Section 10.5.2.

1.2 "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means: (i) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (ii) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.3 "**Agreement**" has the meaning set forth in the preamble hereto.

1.4 "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-bribery or anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.5 "**Anti-Corruption Law Violation**" means a violation of an Anti- Corruption Law relating to the subject matter of this Agreement by or on behalf of Licensee or any of its Affiliates or its or their Sublicensees that would, if it were publicly known, in the reasonable view of AstraZeneca, have a material adverse effect on AstraZeneca or any of its Affiliates or on the reputation of AstraZeneca or any of its Affiliates because of its relationship with Licensee.

1.6 "**Applicable Law**" means applicable laws, rules and regulations, including any rules, regulations, legally binding guidelines or other requirements of the Regulatory Authorities that may be in effect from time to time, including the FFDCA and the Anti-Corruption Laws.

1.7 "Arbitration Notice" has the meaning set forth in Section 10.5.2.

1.8 "**Arbitrators**" has the meaning set forth in Section 10.5.2.

1.9 "**AstraZeneca**" has the meaning set forth in the preamble hereto.

1.10 "AstraZeneca Indemnitees" has the meaning set forth in Section 8.1.

1.11 "**AstraZeneca Know-How**" means the Information Controlled by AstraZeneca or any of its Affiliates as of the Effective Date or that is developed by AstraZeneca or any of its Affiliates at any time during the Term that is (i) not generally known and (ii) reasonably necessary for the Exploitation of the Licensed Compound or a Licensed Product in the Field, but excluding any Information to the extent covered or claimed by published AstraZeneca Patents.

1.12 "**AstraZeneca Patents**" means the Patents set forth on **Schedule 1.12**.

1.13 "**AstraZeneca Regulatory Documentation**" means the Regulatory Documentation Controlled by AstraZeneca or any of its Affiliates and identified on **Schedule 1.13**. At Licensee's request, and subject to AstraZeneca's reasonable discretion, AstraZeneca Regulatory Documentation may also include such other Regulatory Documentation related to the Licensed Compound and Controlled by AstraZeneca or any of its Affiliates, that is necessary for the Development of a Licensed Product in the Field, and specifically identified by the Licensee after the Effective Date.

1.14 "**Auditor**" has the meaning set forth in Section 4.11.

1.15 "**Authorized Generic Version**" means, with respect to a pharmaceutical product, any other pharmaceutical product that (i) is sold under the Drug Approval Application for the first product or any supplement or amendment thereto, (ii) is sold under a different Trademark than the first product and (iii) has a National Drug Code, or NDC, number that differs from the NDC number for the first product (other than on a temporary basis as may be necessary to launch the second product in the Territory).

1.16 "**Breaching Party**" has the meaning set forth in Section 9.2.1.

1.17 "**Business Day**" means a day other than a Saturday or Sunday or a day on which banking institutions in New York are permitted or required to be closed.

1.18 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.

1.19 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.20 "Cause" has the meaning set forth in Section 9.2.4(b).

1.21 "cGMP" means current standards of good manufacturing practice, as amended from time to time, related to the manufacture of Licensed Compound as set forth in the United States Code of Federal Regulations (CFR) 21 CFR Parts 11, 210, 211, 600-800 and 820, European Commission Directive 2003/94/EC, Eudralex Volume 4 and 93/42/EEC.

1.22 "Change of Control" means, with respect to a Party, any of the following events: (a) any Third Party becomes the beneficial owner, directly or indirectly, as a result of a single transaction or a series of related transactions, of 50% or more of the total voting power of all classes of shares of capital stock or other interests of such Party (or, if applicable, a parent of such Party) then outstanding and normally entitled to vote in the general election of directors of such Party ("**Voting Stock**"), (b) such Party (or, if applicable, a parent of such Party) consolidates with or merges into a Third Party, or any such Third Party consolidates with or merges into such Party (or, if applicable, a parent of such Party), in either event pursuant to a transaction in which 50% or more of the total voting power of all Voting Stock of the surviving entity then outstanding is not held by the Persons holding at least 50% of the total voting power of all Voting Stock of such Party (or, if applicable, a parent of such Party) outstanding immediately prior to such consolidation or merger; or (c) such Party (or, if applicable, a parent of such Party) conveys, transfers or leases all or substantially all of its assets to a Third Party.

1.23 "**CMO**" has the meaning set forth in Section 3.6.3.

1.24 "**Combination Product**" means a Licensed Product that is comprised of or contains the Licensed Compound as an active ingredient together with one (1) or more other active ingredients or Delivery Systems and is sold either as a fixed dose/unit or as separate doses/units in a single package.

1.25 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of or sale of a Licensed Product, including activities related to marketing, promoting, distributing and importing such Licensed Product and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization and "**Commercialized**" has a corresponding meaning.

1.26 "**Commercially Reasonable Efforts**" means, with respect to the performance of Development, Commercialization or Manufacturing activities with respect to the Licensed Compound or a Licensed Product by Licensee, the carrying out of such activities using efforts and resources comparable to the efforts and resources commonly used in the research- based biopharmaceutical industry for compounds or products of similar market potential at a similar stage in development or product life. "Commercially Reasonable Efforts" shall be determined on a country-by-country (or region-by-region, where applicable) and indication-by- indication basis, without regard to the particular circumstances of Licensee, including any other product opportunities of Licensee and without regard to any payments owed by Licensee to AstraZeneca under this Agreement.

1.27 "**Confidential Information**" has the meaning set forth in Section 6.1.

1.28 "**Control**" means, with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 2.1), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.29 "**Delivery System**" means any delivery system comprising equipment, instrumentation, one or more devices, or other components designed to assist in, or useful for, the administration of the Licensed Compound.

1.30 "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "**Develop**" means to engage in Development.

1.31 "Dermatological Indications" means diseases of the skin and subcutaneous tissue according to ICD-10 chapter XII.

1.32 "**Dispute**" has the meaning set forth in Section 10.5.

1.33 "**Dollars**" or "**$**" means United States Dollars.

1.34 "**Drug Approval Application**" means a New Drug Application as defined in the FFDCA or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval.

1.35 "**Effective Date**" has the meaning set forth in the preamble hereto.

1.36 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.37 "**European Union**" means the economic, scientific and political organization of member states as it may be constituted from time to time, specifically including any country that was a European Union member state as of the Effective Date, whether or not such country is a participating member as of the applicable time.

1.38 "**Exploit**" means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. "**Exploitation**" means the act of Exploiting a compound, product or process.

1.39 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.40 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.41 "**Field**" means all diagnostic, prophylactic and therapeutic uses of a topical product in humans solely for Dermatological Indications.

1.42 "**Financing**" shall mean the successful completion of the issuance and sale of Series B Convertible Preferred Stock shares by the Licensee which raises gross proceeds to Licensee of at least [***] ([***]).

1.43 "**Financing Period**" shall mean the period of [***] from the Effective Date.

1.44 "**First Commercial Sale**" means, with respect to a Licensed Product and a country, the first sale to a Third Party for monetary value for use or consumption by the end user of such Licensed Product in such country after Regulatory Approval for such Licensed Product has been obtained in such country. Sales for clinical trial purposes and sales prior to receipt of Regulatory Approval for such Licensed Product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.45 "**GAAP**" means, with respect to a Party or its Affiliates or its or their sublicensees, United States generally accepted accounting principles, International Financial Reporting Standards or such other similar national standards as such Party, Affiliates or its or their sublicense adopts, in each case, consistently applied.

1.46 "**Generic Product**" means, with respect to a particular mode of administration and dosage strength of a Licensed Product, any other prescription pharmaceutical product that (i) contains the same active ingredient(s) as such Licensed Product, (ii) has the same mode of administration and dosage strength as such Licensed Product and (ii) is "therapeutically equivalent" as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") (or, with respect to any country in the Territory outside the United States, is similarly substitutable under equivalent Applicable Law in such country), to such Licensed Product.

1.47 "**Hatch-Waxman Act**" means the U.S. "Drug Price Competition and Patent Term Restoration Act" of 1984, as set forth at 21 U.S.C. §355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV).

1.48 "**Improvements**" means any invention, discovery, development or modification with respect to the Licensed Compound or a Licensed Product or relating to the Exploitation thereof, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery (including the development of any Delivery System or enhancement thereto) or dosage of such Licensed Compound or Licensed Product, any discovery or development of any new or expanded indications for such Licensed Compound or Licensed Product, or any discovery or development that improves the stability, safety or efficacy of such Licensed Compound or Licensed Product.

1.49 "**IND**" means (i) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions and (ii) all supplements and amendments that may be filed with respect to the foregoing.

1.50 "**Indemnification Claim Notice**" has the meaning set forth in Section 8.3.

1.51 "**Indemnified Party**" has the meaning set forth in Section 8.3.

1.52 "**Information**" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.53 "**Infringement**" has the meaning set forth in Section 5.3.1.

1.54 "Initial Post-Termination Payment" has the meaning set forth in 9.4.1(b).

1.55 "Inventory" has the meaning set forth in Section 3.6.1.

1.56 "**Invoiced Sales**" has the meaning set forth in the definition of "Net Sales."

1.57 "License Shares" shall have the meaning set forth in Section 4.2.

1.58 "**Licensed Compound**" means the pharmaceutical compound known as

1.59 "**Licensed Product**" means any product that is comprised of or contains the Licensed Compound, alone or in combination with one or more other active ingredients, in any and all topical forms, presentations, dosages and formulations, each of which shall be administered solely by direct application to the skin. For clarity, "Licensed Product" shall include any Delivery Systems that are sold with, or for the administration of, such Licensed Compound.

1.60 "**Licensee**" has the meaning set forth in the preamble hereto.

1.61 "Licensee Indemnitees" has the meaning set forth in Section 8.2.

1.62 "**Licensee Know-How**" means all Information Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or that is developed by Licensee or any of its Affiliates or its or their Sublicensees after the Effective Date and at any time during the Term that is (i) not generally known and (ii) reasonably necessary for the Exploitation of the Licensed Compound or a Licensed Product or any Improvement thereto, but excluding any Information to the extent covered or claimed by published Licensee Patents.

1.63 "**Licensee Patents**" means all of the Patents Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or at any time during the Term that are reasonably necessary or useful for the Exploitation of the Licensed Compound or a Licensed Product or any Improvement thereto.

1.64 "**Losses**" has the meaning set forth in Section 8.1.

1.65 "**Major Market**" means any of the following countries: United States, Italy, Spain, Germany, United Kingdom, France, China or Japan.

1.66 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of a product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.67 "Milestone Event" means each of the event identified as a milestone event in Section 4.3.1 or Section 4.3.2.

1.68 "**Net Sales**" means, with respect to a Licensed Product for any period, the gross amount billed or invoiced by Licensee, its Affiliates or its or their Sublicensees (including distributors of Authorized Generic Versions of Licensed Product(s)) to Third Parties for the sale of a Licensed Product (the "**Invoiced Sales**"), less deductions for:

1.68.1 normal and customary trade, quantity and prompt settlement discounts (including chargebacks and allowances) actually allowed;

1.68.2 amounts repaid or credited by reason of rejection, return or recall of goods, rebates or bona fide price reductions;

1.68.3 freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced;

1.68.4 customs and excise duties and other Taxes or duties related to the sales to the extent that such items are included in the gross amount invoiced;

1.68.5 rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;

1.68.6 the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Licensed Product; and

1.68.7 that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) that Licensee, its Affiliate or its or their Sublicensee, as applicable, allocates to sales of the Licensed Products in accordance with AstraZeneca's, its Affiliate's or its or their Sublicensee's standard policies and procedures consistently applied across its products, as applicable.

Any of the deductions listed above that involves a payment by Licensee, its Affiliates or its or their Sublicensees shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes or as samples, in each case, without charge. Licensee's, its Affiliates' or its or their Sublicensees' transfer of any Licensed Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Licensed Product is consumed or administered by such Affiliate or Sublicensee in the course of its commercial activities. With respect to any Licensed Product that is consumed or administered by Licensee or its Affiliates or its or their Sublicensees, Net Sales shall include any amount billed or invoiced to Third Parties with respect to such consumption or administration, including any services provided in connection therewith.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average invoice price in such country of any Licensed Product that contains the same Licensed Compound(s) as such Combination Product as its sole active ingredient(s) (and without a Delivery System), if sold separately in such country and B is the average invoice price in such country of each product that contains active ingredient(s) other than the Licensed Compound(s) contained in such Combination Product as its sole active ingredient(s) (or the Delivery System on a stand-alone basis if applicable), if sold separately in such country; provided that the invoice price in a country for each Licensed Product that contains only the Licensed Compound(s) and each product that contains solely active ingredient(s) other than the Licensed Compound(s) included in the Combination Product shall be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency. If either such Licensed Product that contains the Licensed Compound(s) as its sole active ingredient or a product that contains an active ingredient (other than the Licensed Product) in the Combination Product as its sole active ingredient(s) (or the Delivery System) is not sold separately in a particular country, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of and all other factors reasonably relevant to the relative value of, the Licensed Compound(s), on the one hand and all of the other active ingredient(s) and Delivery System components, collectively, on the other hand.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Licensee's, its Affiliates' or its or their Sublicensees' existing allocation method; provided that any such allocation to a Licensed Product shall be (i) done in accordance with Applicable Law, including any price reporting laws, rules and regulations and (ii) subject to clause (i), in no event no greater than a pro rata allocation, such that the portion of each of foregoing rebates, discounts and other forms of reimbursements shall not be included as deductions from Invoiced Sales hereunder in any amount greater than the proportion of the undiscounted dollar value of such Licensed Product sold by Licensee, its Affiliates or its or their Sublicensees to Third Parties hereunder compared to the undiscounted dollar value of all the products sold by Licensee, such Affiliates and such Sublicensees to Third Parties to which such foregoing rebate, discount or other form of reimbursement, as applicable, are granted.

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Licensee, its Affiliates or its or their Sublicensees, which must be in accordance with GAAP.

1.69 "**Non-Breaching Party**" has the meaning set forth in Section 9.2.1

1.70 "Non-Prosecuting Party" has the meaning set forth in Section 5.2.2.

1.71 "Notice Period" has the meaning set forth in Section 9.2.1.

1.72 "**Party**" and "**Parties**" have the meaning set forth in the preamble hereto.

1.73 "**Patents**" means: (i) all national, regional and international patents and patent applications, including provisional patent applications; (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted

provisionals and continued prosecution applications; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii) and (iii)); and (v) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.74 "**Payment**" has the meaning set forth in Section 4.7.1.

1.75 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.76 "**Phase II Study**" shall mean (i) a human clinical study conducted in any country that would satisfy the requirements of 21 CFR 312.21(b) and that is designed or intended to explore a variety of doses, dose response and duration of effect to generate initial evidence of clinical safety and activity in a target patient population, or (ii) an equivalent clinical study required by a Regulatory Authority in a jurisdiction outside of the United States. For clarity, the Parties acknowledge and agree that Licensee's proof of concept study "A Phase 1/2a Single Dose and 28- day Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety, Pharmacokinetics and Efficacy of ARQ-151 Cream 0.5% and 0.15% in Adults with Mild to Moderate Chronic Plaque Psoriasis" (NCT03392168), shall be excluded from the definition of Phase II Study and shall not be considered a Phase II Study for purposes of this Agreement.

1.77 "Post-Termination Royalty" has the meaning set forth in Section 9.4.1(b).

1.78 "**Post-Termination Royalty Period"** has the meaning set forth in Section 9.4.1(b).

1.79 "Product Trademarks" means the Trademarks used or to be used by Licensee or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Products in the Territory.

1.80 "**Prosecuting Party**" has the meaning set forth in Section 5.2.2.

1.81 "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product or any Improvement thereto in such country, including, where applicable, (i) pricing or reimbursement approval in such country, (ii) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (iii) labeling approval.

1.82 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of Licensed Compound or Licensed Products or any Improvement thereto in the Territory, including the FDA in the United States and the EMA in the European Union.

1.83 "**Regulatory Documentation**" means: all (i) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (iii) clinical and other data contained or relied upon in any of the foregoing; in each case ((i), (ii) and (iii)) relating to the Licensed Compound or a Licensed Product or any Improvement thereto.

1.84 "**Representatives**" has the meaning set forth in Section 7.6.

1.85 "**Retained Rights**" mean, with respect to the Licensed Compound and Licensed Products, the rights of AstraZeneca, its Affiliates and its and their licensors, (sub)licensees and contractors to (i) perform its and their obligations under this Agreement; (ii) develop, obtain and maintain regulatory approvals for and to Manufacture, Commercialize and otherwise Exploit any compound or product, other than the Licensed Compound or Licensed Products, in any field (including the Field) anywhere in the Territory and (iii) develop, obtain and maintain regulatory approvals for and to Manufacture, Commercialize and otherwise Exploit any compound or product (including the Licensed Compound and Licensed Products) outside the Field anywhere in the Territory; and (iv) Manufacture and Develop and otherwise use the Licensed Compound or Licensed Products in the Field or in the Territory for Exploitation outside of the Field or outside the Territory.

1.86 "**Royalty Term**" means, with respect to each Licensed Product and each country in the Territory, on a country-by-country basis, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country and ending on the latest to occur of: (a) the expiration of the last-to-expire AstraZeneca Patent in such country that contains a Valid Claim; and (b) the 10th anniversary of the First Commercial Sale of such Licensed Product in such country.

1.87 "**Senior Officer**" means, with respect to AstraZeneca, its Vice President, Scientific Partnering & Alliances and with respect to Licensee, its Chief Executive Officer.

1.88 "Specifications" means the written specifications for the Licensed Compound submitted to the applicable Regulatory Authority.

1.89 "**Sublicensee**" means a Person, other than an Affiliate, that is granted a sublicense by Licensee or its Affiliate under the grants in Section 2.1, as provided in Section 2.2, including any distributors of Authorized Generic Versions of a Licensed Product, irrespective of whether such distributor is granted a sublicense hereunder (but otherwise excluding any distributors and/or wholesalers).

1.90 "**Tax**" or "**Taxation**" means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

1.91 "**Tax Authority**" means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs or excise authority, body or official anywhere in the world, authorized to levy Tax.

1.92 "**Term**" has the meaning set forth in Section 9.1.

1.93 "**Terminated Territory**" means each country with respect to which this Agreement is terminated by AstraZeneca pursuant to Section 9.4.2.

1.94 "Termination Notice" has the meaning set forth in Section 9.2.1.

1.95 "**Territory**" means the entire world.

1.96 "**Third Party**" means any Person other than AstraZeneca, Licensee and their respective Affiliates.

1.97 "**Third Party Claims**" has the meaning set forth in Section 8.1.

1.98 "**Third Party Infringement Claim**" has the meaning set forth in Section 5.4.

1.99 "**Third Party Patent Right**" has the meaning set forth in Section 5.6.

1.100 "Trademark" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.101 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.102 "**Valid Claim**" means (i) a claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (a) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (b) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal or (ii) a claim of a pending Patent application that was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application; provided that such pending Patent application has not been pending for more than seven (7) years.

1.103 "**VAT**" has the meaning set forth in Section 4.7.2.

1.104 "Voting Stock" has the meaning set forth in the definition of "Change of Control."

ARTICLE 2
GRANT OF RIGHTS

2.1 Grants to Licensee. Subject to Sections 2.2 and 2.3 and the other terms and conditions of this Agreement, AstraZeneca hereby grants to Licensee:

2.1.1 an exclusive (including with regard to AstraZeneca and its Affiliates) license (or sublicense), with the right to grant sublicenses in accordance with Section 2.2, under the AstraZeneca Patents and the AstraZeneca Know-How, to Exploit the Licensed Compound and Licensed Products in the Field in the Territory; and

2.1.2 an exclusive (including with regard to AstraZeneca and its Affiliates) license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 2.2, under the AstraZeneca Regulatory Documentation as necessary to Exploit the Licensed Compound and Licensed Products in the Field in the Territory.

2.2 Sublicenses. Licensee shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, under the licenses and rights of reference granted in Section 2.1, to its Affiliates and other Persons; *provided* that any such sublicenses shall be consistent with, and expressly made subject and subordinate to, the terms and conditions of this Agreement. Licensee shall cause each Sublicensee to comply with the applicable terms and conditions of this Agreement, as if such Sublicensee were a Party to this Agreement. Licensee hereby (x) guarantees the performance of its Affiliates and permitted Sublicensees and the grant of any such sublicense shall not relieve Licensee of its obligations under this Agreement, and (y) waives any requirement that AstraZeneca exhaust any right, power or remedy, or proceed against any Sublicensee for any obligation or performance under this Agreement prior to proceeding directly against Licensee. A copy of any draft sublicense agreement shall be provided to AstraZeneca prior to its execution and a copy of any sublicense agreement executed by Licensee shall be provided to AstraZeneca within fourteen (14) days after its execution; *provided* that in each case the financial terms of any such sublicense agreement to the extent not pertinent to an understanding of a Party's obligations or benefits under this Agreement may be redacted. Licensee shall provide AstraZeneca with any additional materials reasonably requested by AstraZeneca in order for AstraZeneca to verify that such sublicense is in compliance with the terms and conditions of this Agreement.

2.3 Retention of Rights; Limitations Applicable to License Grants.

2.3.1 Retained Rights of AstraZeneca. Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted or reserved to AstraZeneca pursuant to any other term or condition of this Agreement, AstraZeneca hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors) all right, title and interest in and to the AstraZeneca Patents, the AstraZeneca Know-How and AstraZeneca Regulatory Documentation, in each case, for purposes of performing or exercising the Retained Rights.

2.3.2 No Other Rights Granted by AstraZeneca. Except as expressly provided herein and without limiting the foregoing, AstraZeneca grants no other right or license, including any rights or licenses to the AstraZeneca Patents, the AstraZeneca Know-How, the AstraZeneca Regulatory Documentation or any other Patent or other intellectual property rights.

ARTICLE 3
TRANSITION, DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES.

3.1 Transition Plan. Upon the Effective Date, the Parties will initiate the transfer activities set forth in **Schedule 3.1** (the **"Transition Plan**") and endeavor to complete the Transfer Plan within the timelines set forth therein. Each Party shall bear its own expenses with respect to its obligations and activities under the Transition Plan.

3.2 Development.

3.2.1 Diligence. After the Effective Date, as between the Parties, Licensee shall be solely responsible for all aspects of the Development of the Licensed Compound and Licensed Products in the Field in the Territory. Licensee shall use Commercially Reasonable Efforts to Develop, and obtain and maintain Regulatory Approvals for, Licensed Products for use in the Field in each Major Market. Licensee shall perform or cause to be performed its Development activities hereunder in good scientific manner and in compliance with all Applicable Law by allocating sufficient time, effort, equipment, and skilled personnel to complete such Development activities.

3.2.2 Development Costs. Licensee shall be responsible for all of its costs and expenses in connection with the Development of, and obtaining and maintaining Regulatory Approvals for, the Licensed Products for use in the Field in the Territory. AstraZeneca shall be responsible for all of its costs and expenses in connection with its Retained Rights.

3.2.3 Development Records. Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner, complete and accurate books and records pertaining to Development of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (i) be appropriate for patent and regulatory purposes, (ii) be in compliance with Applicable Law, (iii) properly reflect all work done and results achieved in the performance of its Development activities hereunder, (iv) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement and (v) be retained by Licensee for at least three (3) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. AstraZeneca shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such books and records maintained pursuant to this Section 3.2.3; *provided* that AstraZeneca shall maintain such records and information disclosed therein in confidence accordance with Article 6.

3.2.4 Development Reports. Within thirty (30) days following the end of each Calendar Year during which Licensee is conducting Development activities hereunder, Licensee shall provide AstraZeneca with a detailed written report of such Development activities it has performed, or caused to be performed, since the preceding report, its Development activities in process and the future activities it expects to initiate during the following twelve (12)-month period. Each such report shall contain sufficient detail to enable AstraZeneca to assess Licensee's compliance with its obligations set forth in Sections 3.2.1 including Licensee's, or its Affiliates' or its or their Sublicensees' activities with respect to achieving Regulatory Approvals of Licensed Products in the Territory and clinical study results and results of other Development activities.

3.3 Regulatory Activities.

3.3.1 Regulatory Approvals. Subject to the Retained Rights, Licensee shall have the sole right to prepare, obtain and maintain Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions (including INDs) and to conduct communications with the Regulatory Authorities, for Licensed Products in the Field in the Territory in its name.

3.3.2 Recalls, Suspensions or Withdrawals.

(a) Licensee shall notify AstraZeneca promptly (but in no event later than [***]) following its determination that an event, incident or circumstance has occurred which may result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Licensee shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Field in the Territory, *provided* that prior to the implementation of any such recall, market suspension or market withdrawal due to an event, incident or circumstance (i) related to the Licensed Compound, or (ii) which, in AstraZeneca's reasonable judgment, may otherwise affect a Licensed Product outside the Field, Licensee shall consult with AstraZeneca and shall consider AstraZeneca's comments in good faith.

(b) AstraZeneca shall notify Licensee promptly (but in no event later than [***]) following its determination that an event, incident or circumstance has occurred which may result in the need for a recall, market suspension or market withdrawal of a Licensed Product outside the Field and which, in AstraZeneca's reasonable judgment, affects a Licensed Product in the Field in the Territory.

Such notice shall include the reasoning behind such determination and any supporting facts. Licensee, after consultation with AstraZeneca and if reasonably requested by AstraZeneca, shall initiate a recall, market suspension or market withdrawal of the Licensed Product in the Field in the Territory.

(c) If a recall, market suspension or market withdrawal of a Licensed Product in the Field is mandated by a Regulatory Authority in the Territory, as between the Parties, Licensee shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law.

(d) For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 3.3.2, as between the Parties, Licensee shall be solely responsible for the execution thereof. Subject to Article 8, Licensee shall be responsible for all costs of any such recall, market suspension or market withdrawal.

3.3.3 Pharmacovigilance. Within 120 days after the Effective Date, the Parties shall discuss and agree on how to manage and report adverse events in respect of the Licensed Compound or any Licensed Product and comply with other safety and reporting practices and procedures in compliance with all Applicable Laws. Licensee shall provide AstraZeneca with information in the possession or control of Licensee as necessary for AstraZeneca to comply with its pharmacovigilance responsibilities in respect of the Licensed Compound and the Licensed Products, in the Territory, including, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 600.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States) from pre- clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies, and commercial experiences with the Licensed Compound or a Licensed Product, in each case, in the form reasonably requested by AstraZeneca.

3.3.4 Manufacturing Information. Upon Licensee's reasonable request, AstraZeneca shall provide Licensee one or more letters permitting Licensee to reference the CMC Data for the Licensed Compound solely to the extent necessary for Licensee to prepare, submit, obtain or maintain an IND, Drug Approval Application, or other Regulatory Approval for a Licensed Product in the Field in the Territory.

3.4 Commercialization.

3.4.1 Diligence; Commercialization Costs. After the Effective Date, as between the Parties, Licensee shall be solely responsible for Commercialization of the Licensed Products in the Field throughout the Territory at Licensee's own cost and expense. Licensee shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in each Major Market so as to maximize Net Sales throughout the Territory.

3.4.2 Booking of Sales; Distribution. Licensee shall invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the Licensed Products in the Field in the Territory and perform or cause to be performed all related services. Licensee shall handle all returns, recalls or withdrawals, order processing, invoicing, collection, distribution and inventory management with respect to the Licensed Products in the Territory.

3.4.3 Commercialization Records. Without limitation of Section 4.9, Licensee shall maintain complete and accurate books and records pertaining to Commercialization of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be in compliance with Applicable Law and properly reflect all work done and results achieved in the performance of its Commercialization activities. Such records shall be retained by Licensee for at least three (3) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law.

3.4.4 Commercialization Reports. Without limiting Section 3.4.3, within thirty (30) days following the end of each Calendar Year, commencing upon the First Commercial Sale of a Licensed Product and thereafter, Licensee shall provide to AstraZeneca with written reports of such Commercialization activities it has performed, or caused to be performed, since the preceding report and the future activities it expects to initiate during the following 12-month period. Each such report shall contain sufficient detail to reasonably enable AstraZeneca to assess Licensee's compliance with its obligations set forth in Sections 3.4.1.

3.5 Statements and Compliance with Applicable Law. Licensee shall and shall cause its Affiliates to, comply with all Applicable Law with respect to the Exploitation of Licensed Products. Licensee shall avoid and shall use reasonable efforts to cause its Affiliates and its and their Sublicensees employees, representatives, agents, and distributors to avoid, taking or failing to take, any actions that Licensee knows or reasonably should know would jeopardize the goodwill or reputation of AstraZeneca or the Licensed Products or any Trademark associated therewith. Without limitation to the foregoing, Licensee shall in all material respects conform its practices and procedures relating to the Commercialization of the Licensed Products and educating the medical community in the Territory with respect to the Licensed Products to any applicable industry association regulations, policies and guidelines, as the same may be amended from time to time.

3.6 Supply of Licensed Compound.

3.6.1 If reasonably feasible (as determined solely by AstraZeneca), AstraZeneca may sell to Licensee up to [***] of Licensed Compound (the "**Inventory")** at a cost of [***]. In accordance with the Transition Plan, AstraZeneca shall deliver or have delivered the Inventory to Licensee EXW (Incoterms 2010) at a facility designated by AstraZeneca, together with a certificate of analysis certifying that the Inventory was (a) manufactured in accordance with the Specifications, all Applicable Laws and cGMP, and (b) stored by AstraZeneca prior to delivery in accordance with AstraZeneca's standard procedures, all Applicable Laws and cGMP.

3.6.2 Licensee shall use the Inventory solely for the Development of Licensed Products pursuant to this Agreement and shall not make any Inventory available to any Third Party except as expressly consented to in writing by AstraZeneca.

3.6.3 Upon Licensee's reasonable request, AstraZeneca shall provide a letter permitting Licensee to contact AstraZeneca's Third Party contract manufacturer of the Licensed Compound ("**CMO**") and to negotiate terms and conditions directly with such CMO for the purchase of such additional quantities of the Licensed Compound as may be required by Licensee for its Development and Commercialization of the Licensed Products.

3.6.4 As between the Parties, Licensee shall have the sole responsibility for, at its expense, Manufacturing (or having Manufactured) and supplying the Licensed Compound and Licensed Products for its Development and Commercialization activities in the Territory.

3.7 Subcontracting. Subject to Section 2.2, Licensee may subcontract with a Third Party to perform any or all of its obligations hereunder (including by appointing one or more distributors); provided that (i) no such permitted subcontracting shall relieve Licensee of its obligations hereunder (except to the extent satisfactorily performed by such subcontractor) or any liability and Licensee shall be and remain fully responsible and liable therefor and (ii) the agreement pursuant to which Licensee

engages any Third Party subcontractor must (a) be consistent in all material respects with this Agreement, (b) contain terms obligating such subcontractor to comply with the confidentiality, intellectual property and all other relevant provisions of this Agreement and (c) contain terms obligating such subcontractor to permit AstraZeneca rights of inspection, access and audit substantially similar to those provided to AstraZeneca in this Agreement. Licensee shall ensure that each subcontractor accepts and complies with all of the applicable terms and conditions of this Agreement as if such permitted subcontractor were a Party to this Agreement. Licensee hereby waives any requirement that AstraZeneca exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance under this Agreement prior to proceeding directly against Licensee.

ARTICLE 4
PAYMENTS AND RECORDS

4.1 Cash Payment. In partial consideration of the rights granted by AstraZeneca to Licensee hereunder, Licensee shall pay to AstraZeneca a nonrefundable and non- creditable upfront payment equal to $1.0 million on the Effective Date.

4.2 Equity Payment. Upon closing of the Financing, Licensee shall issue to AstraZeneca $3.0 million worth of its Series B Convertible Preferred Stock (the "**License Shares**") valued at the price per share paid by the investors in the Financing, subject to AstraZeneca's execution of the applicable documents entered into in the Financing between Licensee and the participants in the Financing (the "**Financing Documents**"). The Financing Documents are expected to include the following terms, and should any such term not be included in the Financing Documents, then Licensee will at AstraZeneca's request within thirty (30) days following the closing of the Financing, either amend the Financing Documents to include such term or enter into an additional agreement with AstraZeneca that provides AstraZeneca with substantially the same rights: (i) the pro rata right, based on AstraZeneca's equity ownership percentage in the Licensee (assuming conversion of all outstanding convertible preferred stock into common stock of the Licensee and the exercise of all options outstanding under Licensee's equity incentive plans), to participate in subsequent issuances of equity securities by the Licensee (subject to customary exclusions) to maintain AstraZeneca's equity ownership percentage, (ii) the right to invite one representative of AstraZeneca to attend meetings of the Licensee's board of directors in a nonvoting observer capacity (subject to customary confidentiality agreements and procedures), (iii) the right to receive audited annual financial statements within 120 days following the Licensee's fiscal year-end, (iv) the right to receive unaudited quarterly financial statements within forty-five (45) days following the Licensee's fiscal quarter-end, (v) the right to receive copies of the Licensee's annual business plans and budgets to the extent prepared by or on behalf of the Licensee, (vi) the right to receive written notification of any material defaults of Licensee's obligations under its material contracts or other obligations or the commencement or settlement of any litigation by or against the Licensee, (vii) such other information concerning the Licensee and its business as AstraZeneca may reasonably require from time to time (provided, however, that the Licensee shall not be obligated to provide information pursuant to this clause (vii) that the Licensee reasonably determines in good faith to be a trade secret or the disclosure of which would adversely affect the attorney-client privilege between the Licensee and its counsel), and (viii) all other rights granted to the holders of shares of Series B Convertible Preferred Stock and other terms to which such holders are subject under the Financing Documents (other than any right to appoint a director to Licensee's board of directors), including standard registration rights, customary lock-up restrictions, and right of first refusal and co-sale rights. Notwithstanding anything to the contrary set forth above or in the Financing Documents, if the terms of the Financing include (or are later amended to impose) any pay-to-play provision on the holders of shares of any series of the Licensee's preferred stock, none of the License Shares shall be included in the calculation of AstraZeneca's "pro rata portion" investment obligation with respect to such "pay-to-play" provision. All AstraZeneca's rights and Licensee's obligations under this Section 4.2 will terminate on the earliest of (a) such date as AstraZeneca no longer

holds any of the License Shares or any other shares of any series of Licensee's preferred stock, (b) the consummation of a transaction in which (i) Licensee sells to a third party (other than an Affiliate of Licensee) all or substantially all of Licensee's assets or (ii) a third party acquires from the stockholders of Licensee shares of Licensee's capital stock representing 100% of the outstanding voting power of Licensee (other than a transaction in which the stockholders of Licensee immediately prior to such transaction, continue to hold at least a majority of the voting power of Licensee or the surviving entity (or if the surviving entity is a wholly owned subsidiary, its parent) immediately after such transaction), and (c) the closing of Licensee's first underwritten public offering of the Licensee's common stock under the Securities Act of 1933, as amended.

4.3 Milestones.

4.3.1 Development and Regulatory Milestones. In partial consideration of the rights granted by AstraZeneca to Licensee hereunder, Licensee shall pay to AstraZeneca each of the following nonrefundable, non-creditable milestone payments, which payment shall be fully earned upon the achievement of the applicable Milestone Event:

Development or Regulatory Milestone Event	**Development or Regulatory Milestone Payment**
Report of positive efficacy data in the first Phase II Study of a Licensed Product in the Territory	$2.0 million
[***]	[***]
[***]	[***]

Each milestone payment in this Section 4.3.1 shall be payable only upon the first achievement of the applicable Milestone Event and no amounts shall be due for subsequent or repeated achievements of such Milestone Event, whether for the same or a different Licensed Product.

4.3.2 Commercial Milestones. In partial consideration of the rights granted by AstraZeneca to Licensee hereunder, Licensee shall pay to AstraZeneca each of the following nonrefundable, non-creditable milestone payments, which payments shall be fully earned upon the achievement of the applicable Milestone Event:

Commercial Milestone Event	**Commercial Milestone Payment**
[***]	[***]
[***]	[***]

Each milestone payment in this Section 4.3.2 shall be payable only once upon the first achievement of such Milestone Event and no amounts shall be due for subsequent or repeated achievements of such Milestone Event.

4.3.3 Invoicing; Determination that Milestones Have Occurred.

(a) Licensee shall give AstraZeneca written notice of the achievement of each Milestone Event no later than [***] after such achievement. Upon receipt of such written notice, AstraZeneca shall submit an invoice to Licensee for the full amount of the corresponding milestone payment, which amount shall be payable within [***] after the date of invoice.

(b) If, notwithstanding the fact that Licensee has not provided AstraZeneca with written notice, AstraZeneca believes that a Milestone Event has been achieved, it shall so notify Licensee in writing and the Parties shall promptly meet and discuss in good faith whether such Milestone Event has been achieved. Any dispute under this Section 4.3.3 regarding whether or not a Milestone Event has been achieved shall be subject to resolution in accordance with Section 10.5.

4.4 Royalties.

4.4.1 Royalty Rates. As further consideration for the rights granted to Licensee hereunder, commencing upon the First Commercial Sale of a Licensed Product in the Territory, Licensee shall pay to AstraZeneca, during the Royalty Term, [***] on aggregate Net Sales of all Licensed Products in the Territory during each Calendar Year.

4.4.2 Blended Royalty. Licensee acknowledges that (a) the AstraZeneca Know-How and the Information in the AstraZeneca Regulatory Documentation are proprietary and valuable and that without the AstraZeneca Know-How and AstraZeneca Regulatory Documentation, Licensee would not be able to obtain and maintain Regulatory Approvals with respect to the Licensed Products, (b) such Regulatory Approvals will allow Licensee to obtain and maintain regulatory exclusivity with respect to the Licensed Products in the Field in the Territory, (c) access to the AstraZeneca Know-How and the AstraZeneca Regulatory Documentation has provided Licensee with a competitive advantage in the marketplace beyond the exclusivity afforded by the AstraZeneca Patents and (d) the milestone payments and royalties set forth in Section 4.3 and Section 4.4, respectively, are, in part, intended to compensate AstraZeneca for such exclusivity and such competitive advantage. The Parties agree that the royalty rates set forth in Section 4.4 reflect an efficient and reasonable blended allocation of the value provided by AstraZeneca to Licensee.

4.4.3 Royalty Term. Licensee shall have no obligation to pay any royalty with respect to Net Sales of any Licensed Product in any country after the Royalty Term for such Licensed Product in such country has expired. Upon termination of the Royalty Term with respect to a Licensed Product in any country, the license grants to Licensee in Section 2.1, as applicable, with respect to such Licensed Product shall convert to non- exclusive and shall become fully paid-up with respect to such country.

4.4.4 Royalty Reductions.

(a) In the event that Licensee enters into an agreement with a Third Party in order to obtain a license to a Third Party Patent Right with respect to a Licensed Product that is reasonably necessary to Exploit the Licensed Compound and Licensed Products in the Field in a country in the Territory, Licensee shall be entitled to deduct from royalties payable hereunder in a given Calendar Year with respect to such Licensed Product in such [***] paid to such Third Party in such Calendar Year under such agreement, solely to the extent that such royalties are triggered by sales of such Licensed Product in such country.

(b) If, during the Royalty Term for a Licensed Product in a country in the Territory, the Exploitation of such Licensed Product is not covered by any Valid Claim of any AstraZeneca Patent in such country, then for the remainder of the Royalty Term for such Licensed Product in such country thereafter, the royalty rate set forth in Section 4.4.1 shall be reduced to [***] with respect to Net Sales of such Licensed Product in such country.

4.4.5 Maximum Amount of Royalty Reduction. In no event shall the amounts payable to AstraZeneca under Section 4.4 be reduced by operation of Section 4.4.4 to a royalty rate less than [***].

4.5 Royalty Payments and Reports. Licensee shall calculate all amounts payable to AstraZeneca pursuant to Section 4.4 at the end of each Calendar Quarter, which amounts shall be converted to Dollars, in accordance with Section 4.6. Licensee shall pay to AstraZeneca the royalty amounts due with respect to a given Calendar Quarter within thirty (30) days after the end of such Calendar Quarter. Each payment of royalties due to AstraZeneca shall be accompanied by a statement specifying, on a Licensed Product-by-Licensed Product basis, the amount of Invoiced Sales, Net Sales and deductions taken to arrive at Net Sales attributable to each Licensed Product in each country the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees to account for their Net Sales and to provide such reports with respect thereto, as if such sales were made by Licensee. After receiving such written statement, AstraZeneca shall submit an invoice to Licensee for the royalty amounts due with respect to such Calendar Quarter, which amounts shall be payable within thirty (30) days after the date of invoice. If for any Calendar Quarter there were no Net Sales, Licensee shall notify AstraZeneca and no additional report shall be due under this Section 4.5 for such Calendar Quarter

4.6 Mode of Payment; Offsets. All payments to AstraZeneca under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as AstraZeneca may from time to time designate by notice to Licensee. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), Licensee shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's, as applicable, standard conversion methodology consistent with GAAP.

4.7 Taxes.

4.7.1 General. All amounts payable by Licensee to AstraZeneca pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all taxes, except for any withholding Taxes required by Applicable Law. Except as provided in this Section 4.7, AstraZeneca shall be solely responsible for paying any and all Taxes (other than withholding Taxes required by Applicable Law to be deducted from Payments and remitted by Licensee) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Licensee shall deduct or withhold from the Payments any Taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if AstraZeneca is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, applicable withholding Tax, it may deliver to Licensee or the appropriate governmental authority (with the assistance of Licensee to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Licensee of its obligation to withhold such Tax and Licensee shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that Licensee has received evidence of AstraZeneca's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) prior to the time that the Payments are due. If, in accordance with the foregoing, Licensee withholds any amount, it shall pay to AstraZeneca the balance when due, make timely payment to the proper Taxing authority of the withheld amount and send to AstraZeneca proof of such payment within ten (10) days following such payment.

4.7.2 Value Added Tax. Notwithstanding anything contained in Section 4.7.1, this Section 4.7.2 shall apply with respect to value added tax ("**VAT**"). All Payments are exclusive of VAT. If any VAT is chargeable in respect of any Payments, Licensee shall pay VAT at the applicable rate in respect of any such Payments following the receipt of a VAT invoice in the appropriate form issued by AstraZeneca in respect of those Payments, such VAT to be payable on the later of the due date of the payment of the Payments to which such VAT relates and thirty (30) days after the receipt by Licensee of the applicable invoice relating to that VAT payment. The Parties will issue invoices for all amounts due under this Agreement consistent with indirect Tax requirements.

4.7.3 Gross Up. If either Party assigns this Agreement to an Affiliate or Third Party and, as a result of such assignment, Payments made hereunder are subject to additional withholding Tax, such assigning Party shall be responsible for the resulting additional withholding Taxes; provided, however, that if the non-assigning Party derives a Tax benefit (including through the use of foreign tax credit) determined on a with and without basis as a result of such additional withholding, then the non-assigning Party shall promptly reimburse the assigning Party for the amount of such benefit; provided, further, that the non-assigning Party shall take all commercially reasonable actions necessary to obtain any Tax benefit (including through the use of foreign tax credit) with respect to such additional withholding Taxes and to defend such benefit in a tax audit.

4.8 Interest on Late Payments. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***], as adjusted each Business Day and published by the Federal Reserve Bank of New York through its website (https://apps.newyorkfed.org/markets/autorates/fed%20funds) (or in the event that the U.S. effective federal funds rate is no longer an applicable reference rate, such reasonably equivalent alternative as may be selected by AstraZeneca in its reasonable discretion), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest. Notwithstanding the previous sentence, the payable interest rate shall never be less than [***].

4.9 Financial Records. Licensee shall and shall cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the Commercialization of Licensed Products hereunder, including books and records of Invoiced Sales and Net Sales of Licensed Products, in sufficient detail to calculate and verify all amounts payable hereunder. Licensee shall and shall cause its Affiliates and its and their Sublicensees to, retain such books and records until the later of (i) three (3) years after the end of the period to which such books and records pertain, (ii) the expiration of the applicable tax statute of limitations (or any extensions thereof) and (iii) for such period as may be required by Applicable Law.

4.10 Audit. At the request of AstraZeneca, Licensee shall and shall cause its Affiliates and its and their Sublicensees to, permit AstraZeneca or an independent auditor designated by AstraZeneca and reasonably acceptable to Licensee, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 4.9 to ensure the accuracy of all reports and payments made hereunder. Except as provided below, the cost of this audit shall be borne by AstraZeneca, unless the audit reveals, with respect to a period, a variance of more than five percent (5%) from the reported amounts for such period, in which case Licensee shall bear the cost of the audit. Unless disputed pursuant to Section 4.11 below, if such audit concludes that (i) additional amounts were owed by Licensee, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 4.8 or (ii) excess payments were made by Licensee, AstraZeneca shall reimburse such excess payments, in either case ((i) or (ii)), within sixty (60) days after the date on which such audit is completed by AstraZeneca. Such audit may not be conducted more than once per rolling three hundred sixty five (365) day period without cause.

4.11 Audit Dispute. In the event of a dispute with respect to any audit under Section 4.10, AstraZeneca and Licensee shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than ten (10) days after such decision and in accordance with such decision, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 4.8 or AstraZeneca shall reimburse the excess payments, as applicable.

ARTICLE 5
INTELLECTUAL PROPERTY

5.1 Ownership of Intellectual Property.

5.1.1 Ownership of Technology. As between the Parties, each Party shall own all right, title and interest in and to any and all (a) Information, Improvements and other inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party or its Affiliates or its or their (sub)licensees (or Sublicensee(s)), as applicable, under or in connection with this Agreement, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto and (b) other Information, inventions, Patents and other intellectual property rights that are owned or otherwise controlled (other than pursuant to the license grants set forth in Section 2.1) by such Party or its Affiliates or its or their (sub)licensees (or Sublicensees) (as applicable) outside of this Agreement.

5.1.2 United States Law. The determination of whether Information, Improvements and other inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where such conception, discovery, development or making occurs.

5.1.3 Assignment Obligation. Each Party shall cause all Persons who perform activities for such Party under this Agreement or who conceive, discover, develop or otherwise make any Information, Improvement or other inventions by or on behalf of such Party or its Affiliates or its or their (sub)licensees (or Sublicensees) under or in connection with this Agreement to be under an obligation to assign or grant an exclusive license under their rights in any Information, Improvement and inventions resulting therefrom to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable license or right to obtain such a license, shall be obtained).

5.1.4 Ownership of Product Trademarks. As between the Parties, Licensee shall own all right, title and interest to the Product Trademarks in the Territory.

5.2 Maintenance and Prosecution of Patents.

5.2.1 In General. As between the Parties, (a) AstraZeneca shall have the first right, but not the obligation, through counsel of its choice, to prepare, file, prosecute and maintain the AstraZeneca Patents, including any related interference, re-issuance, re- examination and opposition proceedings with respect thereto, in the Territory, in each case, at AstraZeneca's sole cost and expense and (b) Licensee

shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain the Licensee Patents, including any related interference, re-issuance, re-examination and opposition proceedings with respect thereto, worldwide, in each case, at its sole cost and expense and through counsel of its choice. If, as between the Parties, Astra Zeneca decides not to prepare, file, prosecute or maintain an AstraZeneca Patent in a country in the Territory, AstraZeneca shall provide reasonable prior written notice to Licensee of such intention and Licensee shall thereupon have the right, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution and maintenance of such AstraZeneca Patent at its sole cost and expense in such country.

5.2.2 Cooperation. Each Party shall, and shall cause its Affiliates to, assist the other Party at the reasonable request of the other Party from time to time in connection with its activities set forth in Section 5.2.1. The Party that has the right to prepare, file, prosecute and maintain the AstraZeneca Patents, as applicable (the "**Prosecuting Party**") shall (a) keep the other Party (the "**Non-Prosecuting Party**") informed of all steps to be taken in the preparation and prosecution of all applications filed by it pursuant to Section 5.2.1, (b) furnish the Non-Prosecuting Party with copies of such applications for Patents, amendments thereto and other related correspondence to and from patent offices, including correspondence relating to any office actions, and (c) to the extent reasonably practicable, permit the Non-Prosecuting Party an opportunity to offer its comments on such applications, amendments and other correspondence before making a submission to a patent office, which comments the Prosecuting Party shall consider in good faith. The Non-Prosecuting Party shall offer its comments, if any, promptly.

5.2.3 Patent Term Extension and Supplementary Protection Certificate. As between the Parties, AstraZeneca shall have the sole right to make decisions regarding and AstraZeneca shall have the right to apply for, patent term extensions, in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for the AstraZeneca Patents and with respect to the Licensed Compound and the Licensed Products, in each case including whether or not to do so; *provided* that AstraZeneca shall consult with Licensee to determine the course of action with respect to such filings. Licensee shall provide prompt and reasonable assistance, as requested by AstraZeneca, including by taking such action as patent holder as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

5.2.4 Patent Listings. As between the Parties, Licensee shall have the sole right to make decisions regarding and Licensee shall have the right to make all filings with Regulatory Authorities in the Field in the Territory with respect to the AstraZeneca Patents, and Licensee Patents, including as required or allowed (a) in the United States, in the FDA's Orange Book and (b) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents.

5.3 Enforcement of Patents.

5.3.1 Notice. Each Party shall promptly notify the other Party in writing of (a) any alleged or threatened infringement of the AstraZeneca Patents in any jurisdiction in the Territory or (b) any certification filed under the Hatch-Waxman Act claiming that any AstraZeneca Patents are invalid or unenforceable or claiming that any AstraZeneca Patents would not be infringed by the making, use, offer for sale, sale or import of a product for which an application under the Hatch-Waxman Act is filed or any equivalent or similar certification or notice in any other jurisdiction in the Territory, in each case ((a) and (b)) of which such Party becomes aware (an "**Infringement**").

5.3.2 Enforcement of Patents. As between the Parties, AstraZeneca shall have the first right, but not the obligation, to prosecute any Infringement with respect to the AstraZeneca Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at the AstraZeneca's sole cost and expense, using counsel of AstraZeneca's choice; provided that if AstraZeneca does not take commercially reasonable steps to prosecute such an Infringement (i) within ninety (90) days following the first notice provided above with respect to such Infringement or (ii) provided such date occurs after the first such notice of such Infringement is provided, ten (10) Business Days before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then AstraZeneca shall so notify Licensee and Licensee may prosecute such Infringement at its sole cost and expense. For clarity, Licensee shall have the sole right, but not the obligation, to prosecute any alleged or threatened infringement with respect to the Licensee Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Licensee's sole cost and expense, using counsel of its choice.

5.3.3 Cooperation. If a Party is entitled to, and pursues an action against an Infringement in accordance with this Section 5.3, (a) the other Party shall, and shall cause its Affiliates to, cooperate fully, including being joined as a necessary party to such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours, (b) the Party pursuing any action against an Infringement shall consult with the other Party as to the strategy for such action and (c) such Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken with respect to such action.

5.3.4 Settlement. The Party that is entitled to and pursues an action against an Infringement in accordance with this Section 5.3 shall have the right to control any settlement of such claim; provided that no settlement shall be entered into without the prior consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed) if such settlement would reasonably be expected to have a material adverse effect on the rights or interest of the other Party or any of its Affiliates or impose any costs or liability on or involve any admission by, the other Party or any of its Affiliates.

5.3.5 Cost Recovery. Each Party shall bear its own costs and expenses relating to any Infringement action commenced pursuant to this Section 5.3; provided that the pursuing Party shall reimburse the other Party for the costs and expenses incurred by the other Party for any assistance requested by the pursuing Party for such Infringement action. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described above in this Section 5.3 (whether by way of settlement or otherwise) shall be first, allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the pursuing Party; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to an AstraZeneca Patent is attributable to loss of sales or profits with respect to a Licensed Product, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to such Licensed Product.

5.4 Infringement Claims by Third Parties. If the Exploitation of a Licensed Product in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party alleging infringement by Licensee or any of its Affiliates or its or their Sublicensees, distributors or customers (a "**Third Party Infringement Claim**"), including any defense or counterclaim in connection with an Infringement action initiated pursuant to Section 5.3, the Party first becoming aware of such Third Party Infringement Claim shall promptly notify the other Party in writing. As between the Parties, Licensee shall be responsible for defending any such Third Party Infringement

Claim at its sole cost and expense, using counsel of Licensee's choice. AstraZeneca may participate in any such claim, suit or proceeding with counsel of its choice at its sole cost and expense; provided that Licensee shall retain the right to control such claim, suit or proceeding. AstraZeneca shall, and shall cause its Affiliates to, assist and cooperate with Licensee, as Licensee may reasonably request from time to time, in connection with its activities set forth in this Section 5.4, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that Licensee shall reimburse AstraZeneca for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Licensee shall keep AstraZeneca reasonably informed of all material developments in connection with any such claim, suit or proceeding. Any damages, or awards, including royalties incurred or awarded in connection with any Third Party Infringement Claim defended under this Section 5.4 shall be borne by Licensee.

5.5 Invalidity or Unenforceability Defenses or Actions. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the AstraZeneca Patents by a Third Party of which such Party becomes aware. As between the Parties, AstraZeneca shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the AstraZeneca Patents at its sole cost and expense, using counsel of AstraZeneca's choice and (b) Licensee shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensee Patents at its sole cost and expense, using counsel of Licensee's choice, including, in each case ((a) and (b)), when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Section 5.3. With respect to any such claim, suit or proceeding related to AstraZeneca Patents in the Territory, Licensee may participate in such claim, suit or proceeding with counsel of its choice at its sole cost and expense; provided that AstraZeneca shall retain control of the defense in such claim, suit or proceeding. If AstraZeneca or its designee elects not to defend or control the defense of the applicable AstraZeneca Patents in a suit brought in the Territory or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, Licensee may conduct and control the defense of any such claim, suit or proceeding at its sole cost and expense. Licensee shall, and shall cause its Affiliates to, cooperate fully with respect to such action, including being joined as a party plaintiff in such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that the AstraZeneca shall reimburse Licensee for its reasonable and verifiable costs and expenses incurred in connection therewith. AstraZeneca shall consider in good faith any comments from Licensee and shall keep Licensee reasonably informed of any steps taken with respect to such action.

5.6 Third Party Patent Rights. If in the reasonable opinion of Licensee, the Exploitation of the Licensed Compound or Licensed Product in the Field and in the Territory by Licensee, any of its Affiliates or any of its or their Sublicensees infringes or is reasonably expected to infringe any Patent of a Third Party in any country in the Territory (such right, a "**Third Party Patent Right**"), then, as between the Parties, Licensee shall have the first right, but not the obligation, to negotiate and obtain a license from such Third Party to such Third Party Patent Right as necessary or desirable for Licensee or its Affiliates or its or their Sublicensees to Exploit the Licensed Compound and Licensed Products in the Field in such country; provided that (a) as between the Parties, Licensee shall bear all expenses incurred in connection therewith, including any royalties, milestones or other payments incurred under any such license, (b) any such license shall be limited to the Field in the Territory and provide for the unencumbered right, but not the obligation, to transfer such license to AstraZeneca or any of its Affiliates upon termination or expiration of this Agreement (as provided in Section 9.4) with respect to the applicable country(ies) and (c) Licensee shall obtain the written consent of AstraZeneca prior to entering into any such license (such consent not to be unreasonably withheld, delayed or conditioned).

5.7 Product Trademarks.

5.7.1 Prosecution of Product Trademarks. Licensee shall be responsible for the registration, prosecution and maintenance of the Product Trademarks using counsel of its own choice. All costs and expenses of registering, prosecuting and maintaining the Product Trademarks shall be borne solely by Licensee.

5.7.2 Enforcement of Product Trademarks.

(a) Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.

(b) Licensee shall have the sole right to take such action as Licensee deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory at its sole cost and expense and using counsel of its own choice. Licensee shall retain any damages or other amounts collected in connection therewith; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to a Product Trademark is attributable to loss of sales or profits with respect to a Licensed Product, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to such Licensed Product.

5.7.3 Third Party Claims. Licensee shall have the sole right to defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to a Licensed Product in the Territory at its sole cost and expense and using counsel of its choice. Any damages, or awards, including royalties incurred or awarded in connection with any such claim defended under this Section 5.7.3 shall be borne by Licensee.

5.7.4 Selection of Product Trademarks. Licensee shall not and shall not permit its Affiliates or its or their Sublicensees to use in their respective businesses, any Trademark that (a) contains any term in any Trademark used by AstraZeneca or its Affiliates, or its and their (sub)licensees, unless otherwise agreed to by AstraZeneca in writing, or (b) is confusingly similar to, or a colorable imitation of, any term in any Trademark used by AstraZeneca or its Affiliates, or its and their (sub)licensees.

ARTICLE 6
CONFIDENTIALITY AND NON-DISCLOSURE

6.1 Confidentiality Obligations. At all times during the Term and for a period of ten (10) years following termination or expiration hereof in its entirety, each Party shall and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. "**Confidential Information**" means any technical, business or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on or after the Effective Date, including information relating to the terms of this Agreement (subject to Section 6.2 and Section 6.4), information relating to the

Licensed Compound or any Licensed Product (including the Regulatory Documentation), any Development or Commercialization of the Licensed Compound or any Licensed Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Licensee Know-How and AstraZeneca Know-How, as applicable) or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 6.1 with respect to any Confidential Information shall not include any information that:

6.1.1 is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement by the receiving Party;

6.1.2 can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

6.1.3 is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;

6.1.4 has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party in breach of this Agreement; or

6.1.5 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information. Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

6.2 Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

6.2.1 made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by law, including by reason of filing with securities regulators; *provided*, *however*, that the receiving Party shall first have given prompt notice to the disclosing Party and reasonably assists the disclosing Party in seeking to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided*, *further*, that the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

6.2.2 made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

6.2.3 made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Patent; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

6.2.4 made by or on behalf of AstraZeneca as the receiving Party, in connection with its performance or exercise of its Retained Rights or its rights under this Agreement; or

6.2.5 made by or on behalf of the receiving Party to potential or actual investors, collaboration partners or acquirers as may be necessary in connection with their evaluation of such potential or actual investment, collaboration or acquisition; *provided, however*, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 6 (with a duration of confidentiality and non-use obligations as appropriate that is no less than five (5) years from the date of disclosure).

6.3 Use of Name. Except as expressly provided herein, neither Party shall use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees (or Sublicensees) (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 6.3 shall not prohibit (i) either Party from making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement and (ii) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).

6.4 Public Announcements. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than three (3) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 6.4; *provided* that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

6.5 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of and information regarding, activities under this Agreement. Accordingly, Licensee shall be free to publicly disclose the results of and information regarding, activities under this Agreement, subject to prior review by AstraZeneca of any disclosure of AstraZeneca's Confidential Information for issues of patentability and protection of such Confidential Information, in a manner consistent with Applicable Law and industry practices, as provided in this Section 6.5. Accordingly, prior to publishing or disclosing any Confidential Information of AstraZeneca, Licensee shall provide AstraZeneca with drafts of proposed

abstracts, manuscripts or summaries of presentations that cover such Confidential Information. AstraZeneca shall respond promptly through its designated representative and in any event no later than fifteen (15) days after receipt of such proposed publication or presentation or such shorter period as may be required by the publication or presentation. Licensee agrees to allow a reasonable period (not to exceed thirty (30) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of AstraZeneca. In addition, Licensee shall give due regard to comments furnished by AstraZeneca and such comments shall not be unreasonably rejected.

6.6 Return of Confidential Information. Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement, at the requesting Party's election, (i) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party or (ii) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information (x) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (y) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 6.1.

6.7 Privileged Communications. In furtherance of this Agreement, it is expected that the Parties may, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this Article 6, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between AstraZeneca and Licensee, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of the AstraZeneca Patents and Licensee Patents. In the event of any litigation (or potential litigation) with a Third Party related to this Agreement or the subject matter hereof, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense agreement. In any event, each Party shall consult in a timely manner with the other Party before engaging in any conduct (e.g., producing information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Section 6.7, nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to the Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely by this Section 6.7.

ARTICLE 7
REPRESENTATIONS AND WARRANTIES

7.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party, as of the Effective Date, and covenants, that:

7.1.1 It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

7.1.2 The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;

7.1.3 This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

7.1.4 It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder; and

7.1.5 Neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section. It will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending, relating to the debarment or conviction of it or any such Person performing services hereunder.

7.2 Additional Representations and Warranties of AstraZeneca. AstraZeneca further represents and warrants to Licensee, as of the Effective Date, (a) AstraZeneca Controls the AstraZeneca Patents and the AstraZeneca Regulatory Documentation as of the Effective Date and has the right to grant the licenses specified herein; and (b) AstraZeneca has not received any written claim or demand alleging that the Development or Commercialization of the Licensed Products as contemplated herein infringes any Patent owned by any Third Party.

7.3 Additional Representations and Warranties of Licensee. Licensee further represents and warrants to AstraZeneca, as of the Effective Date, that Licensee: (a) has conducted its own investigation and analysis of (i) the Patent and other proprietary rights of Third Parties as such rights relate to the Exploitation of the Licensed Compound and Licensed Products as contemplated hereunder and (ii) the potential infringement thereof; (b) understands the complexity and uncertainties associated with possible claims of infringement of Patent or other proprietary rights of Third Parties, particularly those relating to pharmaceutical products; and (c) acknowledges and agrees that it is solely responsible for the risks of such claims.

7.4 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON- INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

7.5 ADDITIONAL WAIVER. LICENSEE AGREES THAT: (a) THE ASTRAZENECA PATENTS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND LICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST ASTRAZENECA FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO THE ASTRAZENECA PATENTS; (b) LICENSEE AGREES THAT ASTRAZENECA WILL HAVE NO LIABILITY TO LICENSEE FOR ANY ACT OR OMISSION IN THE PREPARATION, FILING, PROSECUTION, MAINTENANCE, ENFORCEMENT, DEFENCE OR OTHER HANDLING OF THE ASTRAZENECA PATENTS; AND (c) LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE ASTRAZENECA PATENTS HAVE APPLICABILITY OR UTILITY IN LICENSEE'S CONTEMPLATED EXPLOITATION OF THE LICENSED PRODUCTS AND LICENSEE ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.

7.6 Anti-Bribery and Anti-Corruption Compliance. Licensee agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement ("**Representatives**") that for the performance of its obligations hereunder:

7.6.1 Licensee and its Representatives shall comply with the Anti- Corruption Laws and shall not take any action that will, or would reasonably be expected to, cause AstraZeneca or its Affiliates to be in violation of any Anti-Corruption Laws; and

7.6.2 Licensee shall promptly provide AstraZeneca with written notice of the following events: (a) upon becoming aware of any breach or violation by Licensee or its Representative of any representation, warranty or undertaking set forth in Section 7.6.1, or (b) upon receiving notification that it is the target of an investigation or inquiry by a governmental authority for an Anti-Corruption Law Violation or upon receipt of information from any of its Representatives connected with this Agreement that any of them is the target of an investigation or inquiry by a governmental authority for an Anti- Corruption Law Violation.

ARTICLE 8
INDEMNITY

8.1 Indemnification of AstraZeneca. Licensee shall indemnify AstraZeneca, its Affiliates, its or their (sub)licensees and its and their respective directors, officers, employees and agents (the "**AstraZeneca Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (i) the breach by Licensee of this Agreement, including the enforcement of AstraZeneca's rights under this Section 8.1; (ii) the gross negligence or willful misconduct on the part of Licensee or its Affiliates or its or their Sublicensees or its or their distributors or contractors or its or their respective directors, officers, employees or agents in performing its or their obligations under this Agreement; or (iii) the Exploitation by Licensee or any of its Affiliates or its or their Sublicensees or its or their distributors or contractors of any Licensed Product or the Licensed Compound in or for the Territory, except, in each case ((i), (ii) and (iii)), for those Losses for which AstraZeneca has an obligation to indemnify Licensee pursuant to Section 8.2 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

8.2 Indemnification of Licensee. AstraZeneca shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents (the "**Licensee Indemnitees**") and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (i) the breach by AstraZeneca of this Agreement, including the enforcement of Licensee's rights under this Section 8.2; (ii) the gross negligence or willful misconduct on the part of AstraZeneca or its Affiliates or its or their respective directors, officers, employees or agents in performing its obligations under this Agreement; or (iii) the exercise of the Retained Rights by AstraZeneca or its Affiliates or its or their (sub)licensees or its or their distributors or contractors, except, in each case ((i), (ii) and (iii)), for those Losses for which Licensee has an obligation to indemnify AstraZeneca pursuant to Section 8.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

8.3 Indemnification Procedures. All indemnification claims in respect of an AstraZeneca Indemnitee or Licensee Indemnitee shall be made solely by AstraZeneca or Licensee, as applicable (each of AstraZeneca or Licensee in such capacity, the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 8, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims. The indemnifying Party shall have the right to assume the defense of any such Third Party Claim, including the right to select counsel of its choosing and the right to compromise or settle any Third Party Claim, by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice; *provided, however*, that the indemnifying Party shall not make any compromise or settlement admitting fault, subjecting the Indemnified Party to injunctive or other relief, adversely affecting the business of the Indemnified Party or any AstraZeneca Indemnitee or Licensee Indemnitee, as applicable, or incurring any liability on the part of the Indemnified Party or any AstraZeneca Indemnitee or Licensee Indemnitee, as applicable, without the Indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The Indemnified Party shall be entitled to retain counsel of its choice (at its own expense) to participate in, but not control, the defense of any Third Party Claim. Except as provided in the immediately preceding sentence, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party and any AstraZeneca Indemnitee or Licensee Indemnitee, as applicable, in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund if the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party. If it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all reasonable and verifiable costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in accordance with this Section 8.3 in its defense of the Third Party Claim. If the indemnifying Party is required to defend any Third Party Claim, the Indemnified Party shall, and shall cause its employees and agents to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith.

8.4 Special, Indirect and Other Losses. EXCEPT (i) IN THE EVENT THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER Article 6, (ii) AS PROVIDED UNDER SECTION 10.9, (iii) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS Article 8, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY.

8.5 Insurance. Licensee shall have and maintain such types and amounts of insurance covering its Exploitation of the Licensed Compound and Licensed Products as is (i) normal and customary in the pharmaceutical industry generally for parties similarly situated and (ii) otherwise required by Applicable Law. Upon request by AstraZeneca, Licensee shall provide to AstraZeneca evidence of its insurance coverage, including copies of applicable insurance policies. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to Licensee, then Licensee shall continue to maintain such insurance after the expiration or termination of this Agreement in its entirety for a period of five (5) years.

ARTICLE 9
TERM AND TERMINATION

9.1 Term and Expiration. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until the date of expiration of the last Royalty Term for the last Licensed Product (such period, the "**Term**"). Following the expiration (but not earlier termination) of the Royalty Term for a Licensed Product in a country, the grants in Section 2.1 shall become non-exclusive, fully-paid, and irrevocable for such Licensed Product in such country. For clarity, upon the expiration of the Term, the grants in Section 2.1 shall become non-exclusive, fully-paid, and irrevocable in their entirety.

9.2 Termination.

9.2.1 Material Breach. If either Party materially breaches any of its obligations under this Agreement (such Party, the "**Breaching Party**"), in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non- Breaching Party may terminate this Agreement by providing ninety (90) days' (or, with respect to a payment breach, ten (10) days') (the "**Notice Period**") prior written notice (the "**Termination Notice**") to the Breaching Party and specifying the breach and its claim of right to terminate; *provided* that (a) the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period, (b) if the breach is capable of being cured, but cure of such breach (other than non-payment) cannot reasonably be effected within such ninety (90)-day period, the breaching Party shall deliver to the non-breaching Party a plan reasonably calculated to cure such breach within a reasonable time frame, but in any event within one hundred eighty (180) days, and so long as the breaching Party is diligently carrying out such plan, the non-breaching Party shall not have the right to terminate this Agreement during such 180-day cure period; and (c) with respect to an uncured material breach of Licensee's diligence obligations under Section 3.2.1 or Section 3.4.1, as applicable, AstraZeneca shall have the right to terminate this Agreement, in its sole discretion, solely with respect to the country(ies) affected by such breach; further *provided* that, if the breach affects two (2) or more Major Markets, AstraZeneca shall have the right to terminate this Agreement, in its sole discretion, in its entirety.

9.2.2 Termination by AstraZeneca.

(a) If Licensee fails to close the Financing and issue the License Shares to AstraZeneca during the Financing Period, AstraZeneca shall have the right to immediately terminate this Agreement in its entirety, including the rights of any Sublicensees, upon written notice to Licensee.

(b) If Licensee or any of its Affiliates or Sublicensees, anywhere in the Territory, institutes, prosecutes or otherwise participates in (or in any way aids any Third Party in instituting, prosecuting or participating in), at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action or cause of action for declaratory relief, damages or any other remedy or for an enjoinment, injunction or any other equitable remedy, including any interference, re-examination, opposition or any similar proceeding, alleging that any claim in a AstraZeneca Patent is invalid, unenforceable or otherwise not patentable or would not be infringed by Licensee's activities absent the rights and licenses granted hereunder, AstraZeneca shall have the right to immediately terminate this Agreement in its entirety, including the rights of any Sublicensees, upon written notice to Licensee.

(c) If Licensee permanently ceases development of all Licensed Products and a Licensed Product is not being commercialized in the Territory by or on behalf of Licensee, AstraZeneca shall have the right to terminate this Agreement in its entirety by providing one hundred twenty (120) days' prior written notice to Licensee; *provided* that the normal pauses or gaps between or following clinical studies or other studies for the analysis of data, preparation of reports and design of future clinical studies or preparation of regulatory filings and other customary development functions not constituting clinical studies do not constitute a cessation of development.

9.2.3 Termination for Insolvency. If either Party or any of its Affiliates (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within 60 days of the filing thereof or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

9.2.4 Termination by Licensee.

(a) Licensee shall have the right to terminate this Agreement in its entirety without any cause at any time by giving at least one hundred twenty (120) days' advance written notice to AstraZeneca of such termination; *provided* that, Licensee shall remain obligated to meet its obligations hereunder and under Applicable Law, including with respect to conducting or funding any Development and Commercialization activities, during such one hundred twenty (120) day period, or such longer period as may be required under Applicable Law.

(b) Licensee shall have the right to terminate this Agreement in its entirety upon written notice to AstraZeneca for Cause. For purposes of this Agreement, "**Cause**" means (i) a material risk for harm based upon the observation of serious adverse effects in humans after a Licensed Product has been administered to or taken by humans, such as during a clinical trial or after the launch of the Licensed Product and/or (ii) any other situation where, as a result of feedback received from, or other interactions with, Regulatory Authorities, the Development of a Licensed Product in the Field in the Territory is no longer commercially reasonable.

9.3 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Licensee or AstraZeneca are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

9.4 Consequences of Termination.

9.4.1 Termination in its Entirety. In the event of a termination of this Agreement in its entirety for any reason:

(a) all rights and licenses granted by AstraZeneca hereunder shall immediately terminate, including, for clarity, any sublicense granted by Licensee pursuant to Section 2.2 (provided that upon such termination, any such sublicense will continue as a direct license between AstraZeneca and the applicable Sublicensee, subject to AstraZeneca's written consent, which consent shall not be unreasonably withheld, conditioned or delayed);

(b) in any case of any termination of this Agreement other than by Licensee pursuant to Section 9.2.1 (where AstraZeneca is the Breaching Party) or 9.2.4(b), Licensee shall pay to AstraZeneca an amount equal to the greater of (i) [***] ("**Initial Post-Termination Payment**") or (ii) [***] ("**Post-Termination Royalty**") during the [***] ("**Post-Termination Royalty Period**"), [***]. For avoidance of doubt, in the situation where the first Regulatory Approval in the Territory has occurred prior to termination, the Post-Termination Royalty (to the extent the Post-Termination Royalty accrued prior to such termination exceeds the Initial Post-Termination Payment) shall be payable within thirty (30) days after the effective date of termination, and the remainder, if any, shall be payable on a quarterly basis, in accordance with Section 4.5, during the remainder of the Post-Termination Royalty Period.

(c) The Parties acknowledge and agree that the payments set forth in Section 9.4.1(b) are the only payments due to AstraZeneca due in connection with any termination of the Agreement (other than amounts that are outstanding as of the termination date in accordance with the terms of the Agreement), and, without limiting the foregoing, such payments shall constitute Licensee's sole liability and AstraZeneca's sole remedy for Licensee's failure to comply with the diligence obligations under Section 3.2.1 and Section 3.4.1.

9.4.2 Termination in a Terminated Territory. In the event of a termination of this Agreement with respect to a Terminated Territory by AstraZeneca pursuant to Section 9.2.1 (but not in the case of any termination of this Agreement in its entirety):

(a) all rights and licenses granted by AstraZeneca hereunder, and any sublicense granted by Licensee pursuant to Section 2.2, (i) shall automatically be deemed to be amended

to exclude, if applicable, the right to market, promote, detail, distribute, import, sell for commercial use, offer for commercial sale, file any Drug Approval Application for, or seek any Regulatory Approval for Licensed Products in such Terminated Territory and (ii) shall otherwise survive and continue in effect in such Terminated Territory solely for the purpose of furthering any Commercialization of the Licensed Products in the Territory or for any ongoing Development or Manufacturing in support thereof;

(b) the Parties shall negotiate in good faith a non-exclusive, royalty-bearing license grant and right of reference from Licensee to AstraZeneca under the Licensee Patents, Licensee Know-How, the Product Trademarks, and Regulatory Documentation (including any Regulatory Approvals) then Controlled by Licensee or any of its Affiliates that, in each case, are necessary for AstraZeneca to Develop or Commercialize the Licensed Compound or Licensed Products, or any Improvements thereto, that are or have been the subject of Development or Commercialization hereunder as of the effective date of termination, in each case solely in the Terminated Territory.

9.5 Remedies. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

9.6 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Articles 1, 8, 10 and Sections 3.2.3 (for the period set forth therein), 3.2.4 (with respect to activities during the Term), 3.3.2 (for sales during the Term), 3.4.3 (for the period set forth therein), 3.4.4 (with respect to activities during the Term), 4.3 (with respect to Milestones achieved during the Term), 4.4 (with respect to Net Sales made during the Term), 4.5 (for final accounting), 4.6 through 4.8 (with regard to accrued but unpaid amounts), 4.9 (for the period set forth therein), 4.10, 4.11, 5.1, 5.7.4, 6.1, 6.2, 9.4, 9.5 and this 9.6 of this Agreement shall survive the termination or expiration of this Agreement for any reason. If this Agreement is terminated with respect to a Terminated Territory but not in its entirety, then following such termination, the foregoing provisions of this Agreement shall remain in effect with respect to the Terminated Territory (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety, or as otherwise necessary for any of AstraZeneca and its Affiliates and its and their (sub)licensees to exercise their rights in the Terminated Territory) and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the Terminated Territory and be of no further force and effect.

ARTICLE 10
MISCELLANEOUS

10.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within thirty (30) days after such occurrence by giving written notice to the other Party stating

the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. Without limitation to the foregoing, if the suspension of performance continues for ninety (90) days after the date of the occurrence and such suspension of performance would constitute a material breach of this Agreement in the absence of this Section 10.1, AstraZeneca shall have the right to terminate this Agreement pursuant to Section 9.2 without regard to this Section 10.1, except that in such event no cure period shall apply and AstraZeneca shall have the right to effect such termination upon written notice to Licensee, in its sole discretion.

10.2 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

10.3 Assignment. Neither Party may assign its rights or, except as provided in Section 3.7, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except that (a) AstraZeneca shall have the right, without such consent, to (i) perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates or its or their (sub)licensees and (ii) assign any or all of its rights and delegate any or all of its obligations under this Agreement to any Person who acquires all or substantially all of the business to which this Agreement relates, and (b) each Party shall have the right, without such consent, to assign any or all of its rights and delegate any or all of its obligations under this Agreement to any of its Affiliates or its or their (sub)licensees or to any successor in interest as a result of a Change of Control; *provided* that each Party shall provide written notice to the other Party within thirty (30) days after such assignment or delegation. Any permitted successor of a Party or any permitted assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 10.3 shall be void and of no effect.

10.4 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

10.5 Dispute Resolution.

10.5.1 Except as provided in Section 4.11 or 10.9, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of ten (10) Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

10.5.2 If such Senior Officers are unable to resolve any such Dispute within such ten (10) – Business Day period, either Party shall be free to institute binding arbitration in accordance with this Section 10.5.2 upon written notice to the other Party (an "**Arbitration Notice**") and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the "**Arbitrators**"). Each of Licensee and AstraZeneca shall promptly select one Arbitrator, which selections shall in no event be made more than thirty (30) days after the date of the Arbitration Notice. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Licensee and the Arbitrator chosen by AstraZeneca, but in no event more than thirty (30) days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; *provided* that the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the dispute. The arbitration shall be administered by the American Arbitration Association ("**AAA**") (or its successor entity) in accordance with the then-current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within fifteen (15) days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with Applicable Law in the State of Delaware or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

10.5.3 Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 10.5, and shall pay an equal share of the fees and costs of the Arbitrators, and all other general fees related to any arbitration described in Section 10.5.2; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses), or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 10.5.2, as applicable, is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of such pending arbitration proceeding. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding. All arbitration proceedings and decisions of the Arbitrator, as applicable, under Section 10.5, shall be deemed Confidential Information of both Parties under Article 6.

10.6 Governing Law, Jurisdiction and Service.

10.6.1 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

10.6.2 Jurisdiction. Subject to Section 10.5 and Section 10.9, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of Delaware for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

10.6.3 Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of Delaware and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

10.6.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 10.7.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

10.7 Notices.

10.7.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, addressed to the Parties at their respective addresses specified in Section 10.7.2 (or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 10.7.1). A copy of the communication shall also be e-mailed to the Parties as specified in Section [ ]. Such Notice shall be deemed to have been given as of the date delivered by hand or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 10.7.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

10.7.2 Address for Notice.

If to Licensee, to:

Arcutis, Inc.
70 Willow Road
Suite 200
Menlo Park, CA 94025
Attention: Chief Executive Officer

with an e-mail copy (which shall not constitute notice) to:

tfw@arcutis.com

If to AstraZeneca, to:

AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilminton, DE 19803
Attention: Vice President, Scientific Partnering & Alliances

with an e-mail copy (which shall not constitute notice) to:

legalnotices@astrazeneca.com

10.8 Entire Agreement; Amendments. This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding on the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

10.9 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Article 5 and Article 6 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Articles, the Non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Non-breaching Party may be entitled in law or equity. Nothing in this Section 10.9 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

10.10 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

10.11 No Benefit to Third Parties. Except as provided in Article 8, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

10.12 Further Assurance. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

10.13 Relationship of the Parties. It is expressly agreed that AstraZeneca, on the one hand and Licensee, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither AstraZeneca, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action, that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

10.14 References. Unless otherwise specified, (i) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

10.15 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

10.16 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the date first written above.

ASTRAZENECA AB

By: /s/ Anders Holmén
Anders Holmén
Vice President, Pharmaceutical Sciences

ARCUTIS, INC.

By: /s/ Frank Watanabe
Name: Frank Watanabe
Title: President and CEO

Schedule 1.12
AstraZeneca Patents

[***]

Schedule 1.13

AstraZeneca Regulatory Documentation

[***]

45

Exhibit 10.11

CONFIDENTIAL

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED, AND HAS BEEN MARKED WITH "[***]" TO INDICATE WHERE OMISSIONS HAVE BEEN MADE.

EXECUTION VERSION 2 JANUARY 2018

EXCLUSIVE OPTION AND LICENSE AGREEMENT

This EXCLUSIVE OPTION AND LICENSE AGREEMENT (this "***Agreement***") is entered into as of January 4th, 2018 (the "***Effective Date***"), by and between Arcutis, Inc., a United States corporation incorporated in the State of Delaware with offices at 70 Willow Road, Suite 200, Menlo Park, CA 94025 ("***Arcutis***") and Jiangsu Hengrui Medicine Co., Ltd., a Chinese corporation with offices at 7 Kunlunshan Road, Economy and Technology Development Zone, Lianyungang, Jiangsu, China ("***Hengrui***"). Hereinafter, "***Parties***" shall mean Arcutis and Hengrui together, and "***Party***" shall mean Arcutis or Hengrui, as the context requires.

RECITALS

WHEREAS, Arcutis is a biopharmaceutical company in the business of developing and commercializing therapeutic products;

WHEREAS, Hengrui Controls the active pharmaceutical ingredient named by Hengrui as SHR0302; and

WHEREAS, Arcutis is interested in conducting preliminary studies on SHR0302 and related compounds as described herein with an option to exclusively license the same for development of topical therapeutic products.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

ARTICLE I
DEFINITIONS

1.1 "***Affiliate***" means any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Party or other entity in question. As used in this definition of "Affiliate," the term "control" shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise.

1.2 "***Applicable Law***" means, with respect to any Party or other person or entity, any federal, state or local law (statutory, common or otherwise), constitution, treaty, convention, ordinance, code, rule, regulation, executive order, injunction, judgment, decree, ruling or other similar requirement enacted, adopted, promulgated or applied by a Governmental Authority that is binding upon or applicable to such Party, person or entity.

1.3 "***Business Day***" means any day other than a Saturday, a Sunday or a day on which banks in New York, New York are authorized or obligated by law or governmental order to close.

1.4 "***Calendar Quarter***" means each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, and December 31.

1.5 "***Calendar Year***" means the period of time beginning on January 1 and ending December 31, except for (a) the first year which shall begin on the Effective Date and end on December 31 and (b) any year in which this Agreement is terminated or expires prior to December 31, in which case the Calendar Year shall be from January 1 of that year to the date of expiration or termination.

1.6 "***Commercially Reasonable Efforts***" shall mean. with respect to a Party's obligations under this Agreement, including to develop, commercialize or manufacture the Licensed Products, those efforts and resources dedicated are consistent with such Party's efforts in pursuing the development, commercialization or manufacture of any other comparable pharmaceutical products that are of similar market potential as Licensed Product, taking into account all relevant factors including product labeling or anticipated labeling, present and future market potential, past performance of such Licensed Product, financial return, medical and clinical considerations, present and future regulatory environment and competitive market conditions. Further, Commercially Reasonable Efforts with respect to a Licensed Product requires that a Party: (a) set and seek to achieve reasonable objectives for carrying out its obligations in a timely manner, subject to adjustment or modification of such objectives taking into account all relevant factors, and (b) make and implement decisions and allocate appropriate resources for the purpose of advancing progress with respect to achieving such objectives.

1.7 "***Control***" means (as an adjective or as a verb including conjugations and variations such as "***Controls***" "***Controlled***" or "***Controlling***") (a) with respect to Patent Rights. the possession by a Party of the ability to grant a license or sublicense of such Patent Rights without violating the terms of any agreement or arrangement between such Party and any other party and (b) with respect to scientific or technical information, results, materials, and data, whether or not patentable, the possession by a Party of the ability to supply the same to the other Party as provided herein without violating the terms of any agreement or arrangement between such Party and any other party. For clarity, Control may be based upon ownership as well as upon license or other rights.

1.8 "***Cover***" means (as an adjective or as a verb including conjugations and variations such as "Covered." "Coverage" or "Covering"). with respect to a claim of a pending or issued patent, that the developing, making. using, offering for sale, promoting, selling, exporting or importing of a given compound, formulation or product would infringe such claim in the absence of a license under or ownership in the Patent Rights to which such claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular claim shall be made on a country-by-country basis.

1.9 "***Dollars***" or "***$***" means the legal tender of the U.S.

1.10 "***Exploit***" and "***Exploitation***" mean to make, have made, import, use, sell, or offer for sale, reproduce, modify, publish, distribute, including to sublicense (through multiple tiers), research, develop, commercialize, register, hold, or keep (whether for disposal or otherwise), have used, transport, distribute, promote, market, or have sold or otherwise dispose of.

1.11 "***Field***" means any topical formulations for the treatment of skin diseases, disorders and conditions, excluding any other formulations such as for ingestion or injection (either subcutaneous or intravenous or otherwise).

1.12 "***First Commercial Sale***" means on a country-by-country basis, the first sale of a Licensed Product by a Selling Party following the receipt of all Regulatory Approval required for the commercial sale of such Licensed Product in such country.

1.13 "***Generic Competition***" means with respect to a Licensed Product in a country, when one or more Generic Product(s) are being marketed in such country and all Licensed Patent Rights Covering such Licensed Product in such country have expired.

1.14 "***Generic Product***" means a product (a) whose active pharmaceutical ingredient is rated as equivalent to the Licensed Product being sold in a country, (b) that obtained Regulatory Approval solely by means of establishing such equivalence to such Licensed Product, and (c) that is legally marketed in such country by an entity other than a Selling Party hereunder.

1.15 "***Governmental Authority***" means any transnational, or domestic or foreign federal, state or local, governmental authority, department, court, agency or official, including any political subdivision thereof.

1.16 "***IND***" shall mean an Investigational New Drug application. or similar application to commence human clinical testing of a Licensed Product for use in the Field submitted to the U.S. Food and Drug Administration pursuant to Title 21 of the Code of Federal Regulations, Part 312, or its foreign equivalent.

1.17 "***Invention***" means any new and nonobvious process, method, composition of matter, article of manufacture, result, data, know-how, software, works of authorship, or information, whether or not patentable or copyrightable.

1.18 "***Licensed Compound***" means the chemical compound or compounds that are or have been at any time prior to or as of the Effective Date referred to internally or externally by Hengrui as "SHR0302".

1.19 "***Licensed Know-How***" means all scientific or technical information, results, materials, and data, including safety and efficacy data, formulae, procedures, final and preliminary protocols, techniques, and results (negative or positive) of experimentation and testing, whether or not patentable that, in each case. are (a) Controlled by Hengrui or its Affiliates at any time prior to or as of the Effective Date or at any time during the Term of this Agreement and (b) materially related to a Licensed Compound or otherwise necessary for the Exploitation of Licensed Products.

1.20 "***Licensed Patent Rights***" means all Patent Rights in and to (a) the patents and patent applications listed in Exhibit A hereto, together with any and all current or future divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications claiming priority to any of such listed patents or patent applications or to any application to which such listed patents or patent applications claim priority, and any and all patents that have issued or in the future issue from any of the foregoing, including utility models, petty patents and design patents and certificates of invention, and any and all adjustments, extensions or restorations by existing or future adjustment, extension or restoration mechanisms, including revalidations, reissues, re-examinations, term adjustments, and extensions (including any supplementary protection certificates and the like), of any thereof; and (b) any and all foreign counterparts of any of the foregoing in any nation, jurisdiction, or patent authority in the Territory.

1.21 "***Licensed Product***" means on a country b) country basis, any pharmaceutical product or component that comprises a Licensed Compound.

1.22 "***Licensed Technology***" means either or both of the Licensed Patent Rights and the Licensed Know-How.

1.23 "***Net Sales***" means the gross invoiced sales amount of Licensed Products paid to a Selling Party for the sale or other commercial disposition of Licensed Products in the Territory during the Royalty Term applicable to the country of sale or disposition, less the following items listed to the extent actually taken or incurred with respect to such sale, in accordance with standard allocation procedures, allowance methodologies and accounting methods consistently applied:

(a) customary credits or allowances for Licensed Product returns during such quarter, including, but not limited to, credits for returned, recalled, damaged, unsold, or short-dated Licensed Product, allowances granted or included in the invoice, discounts, customer program accruals (overbills, administrative fees, Third Party rebates, sales brokerage, and volume rebates), other adjustments and rebates, including but not limited to Medicaid and other state or governmental rebates, charge backs, floor stock adjustments, and similar items that may be estimated in accordance with GAAP/IFRS;

(b) import, export, sales (including VAT or its equivalent) and excise taxes, customs duties, other consumption taxes, or other governmental charges to the extent actually included in gross sales; and

(c) costs of freight, insurance, packaging costs and other transportation charges to the extent actually included in gross sales.

Sales among the Selling Party and its Affiliates or Sublicensees shall he excluded from the computation of Net Sales, except where such Affiliates or Sublicensees are end users, and sales from one Party or its Affiliate or Sublicensee to the other Party or its Affiliate or Sublicensee for use in development activities, in the further manufacture of Products. or for resale shall be excluded from the computation of Net Sales; provided, however, in each case that any subsequent resale shall be included within Net Sales. In addition, the Selling Party may exclude

from Net Sales a reasonable provision for uncollectible accounts, consistently applied across all product lines of the particular Party, until such amounts arc actually collected. The computation of Net Sales shall not include Licensed Products provided for use in clinical trials or other research or development activities, or Licensed Products given as samples or for humanitarian or charitable purposes, in each case at or below cost.

For purposes of determining whether a given sale occurs during a computation period, a Licensed Product will be considered sold as of the date of shipment by the applicable Selling Party to its customers, wholesalers, or distributors, as applicable.

No multiple payments on the same Net Sales shall be payable hereunder, regardless of whether the relevant Licensed Products are covered by more than one Valid Claim or otherwise.

If a Licensed Product consists of at least one Licensed Compound and at least one active ingredient that is not a Licensed Compound, then for purposes of the calculation of Net Sales of such Licensed Product, such Net Sales, prior to the royalty calculations set forth above, first shall be multiplied by the fraction A/(A+B), where A is the market value of the Licensed Compound(s) in such Licensed Product as reasonably determined and agreed by Arcutis and Hengrui, and B is the market value of the non-Licensed Compound(s) as reasonably determined and agreed by Arcutis and Hengrui, it being understood that the amount resulting from such calculation shall be the "Net Sales" for the applicable combination Licensed Product which shall be determined on a country-by-country basis. In the case that market values of A and B cannot be reasonably determined and agreed by Arcutis and Hengrui, both agree to, on a country-by country basis, select most comparable marketed products of A and B to determine a median market value for each.

1.24 "***Option Period***" means the period of time commencing on the Effective Date and ending eighteen (18) months after the Effective Date.

1.25 "***Option Period Studies***" means studies of the nature and for the purposes outlined in **Exhibit B** hereto, intended to allow Arcutis determine whether or not it will exercise the Option.

1.26 "***Option Period Study Results***" means any and all Inventions, scientific or technical information, results, materials, and data, including safety and efficacy data, formulae procedures, final and preliminary protocols, techniques, and results (negative or positive) of experimentation and testing, that are first discovered, made, or developed in the course of conducting the Option Period Studies.

1.27 "***Patent Controversy***" means any dispute between the Parties to the extent that it involves an issue relating to the inventorship, claim scope or interpretation, infringement, enforceability, patentability, defense. or validity of any Patent Right hereunder, and including any such issues relevant to any prosecution activities hereunder.

1.28 "***Patent Right(s)***" means all rights and privileges in, to, or under any patent or pending patent application anywhere in the world.

1.29 "***Phase I Clinical Trial***" shall mean a human clinical trial in any country in the Territory, which provides for the first introduction into humans of a Licensed Product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity, or pharmacokinetics. as described in 21 CFR 312.21(a), or its foreign equivalent.

1.30 "***Phase II Clinical Trial***" shall mean a human clinical trial in any country in the Territory, which is prospectively designed to establish the safety, dose ranging and efficacy of a Licensed Product, as further defined in 21 CFR 312.21(b), or its foreign equivalent.

1.31 "***Phase III Clinical Trial***" shall mean a human clinical trial in any country in the Territory, the results of which could be used to establish safety and efficacy of a Licensed Product as a basis to satisfy the requirements of 21 CFR 312.21(c), or its foreign equivalent.

1.32 "***POC Study***" means a proof-of-concept clinical study to be conducted as part of the Option Period Studies.

1.33 "***Prosecute***" means to have primary responsibility for preparing, filing. prosecuting (including interference and opposition proceedings) and maintaining (including interferences, reissue, re-examination, post-grant reviews, inter-partes reviews, derivation proceedings and opposition proceedings), including discontinuing or abandoning Patent Rights.

1.34 "***Regulatory Approval***" means with respect to a country, extra-national territory, province, state, or other regulatory jurisdiction, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary in order to Exploit a product in such country, state, province, or some or all of such extra-national territory or regulatory jurisdiction, which shall include any pricing and reimbursement approvals.

1.35 "***Regulatory Authority***" means, with respect to a particular country, extra-national territory, province, state, or other regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval, including but not limited to the FDA, the EMA, the European Commission, and the MHLW, and in each case including any successor thereto.

1.36 "***Regulatory Materials***" means regulatory applications, submissions, dossiers, notifications, registrations, Regulatory Approvals and or other filings made to or with, or other approvals granted by, a Regulatory Authority that are necessary or reasonably desirable in order to Exploit a Licensed Product in a particular country or regulatory jurisdiction, including INDs, MAAs and NDAs.

1.37 "***Royalty Term***" means, with respect to a given Licensed Product sold or commercially distributed in a given country, on a country-by-country basis, the time period commencing on the date of the First Commercial Sale of the Licensed Product in such country and ending on the later of (i) the expiration of the last Valid Claim in such country Covering such Licensed Product or its use, and (ii) the expiration of the last applicable period of effective regulatory-based exclusivity, if any, for such Licensed Product in such country.

1.38 "***Selling Party***" means, as applicable, Arcutis, its Affiliate, its Sublicensee, or an Affiliate of a Sublicensee.

1.39 "***Territory***" means (a) the United States, (b) Japan, (c) the countries of the European Union as of the Effective Date (including the United Kingdom and all of its component nations, as of the Effective Date), whether or not remaining in the European Union following the Effective Date, (d) any other country that becomes part of the European Union at any time following the Effective Date, and (e) any territory or possession of any of the foregoing.

1.40 "***Third Party***" means a person or entity other than (a) Arcutis or any of its Affiliates or (b) Hengrui or any of its Affiliates.

1.41 "***Valid Claim***" means (a) a claim of any pending patent application included in the Licensed Patent Rights, that has not been pending in excess of fifteen (15) years, and/or(b) a claim of an issued and unexpired patent included within the Licensed Patent Rights that which has not been held permanently revoked, unenforceable, or invalid by an unappealable (or unappealed within the time allowed for appeal) decision of a court or other Governmental Authority of competent jurisdiction, and which has not been dedicated to the public, abandoned, or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

ARTICLE II
OPTION AND OPTION PERIOD STUDIES

2.1 Upfront Payment. Within thirty (30) Business Days following the Effective Date of this Agreement, Arcutis will pay Four Hundred Thousand US Dollars ($400,000) to Hengrui (the "***Upfront Payment***".). which amount shall be non-creditable and non-refundable.

2.2 Transfer of Data and Information. Within thirty (30) Business Days following Hengrui's receipt of the Upfront Payment, Hengrui shall without charge deliver to Arcutis, in English, all Licensed Know-How in Hengrui's possession or otherwise readily available to it; provided, however, that Hengrui shall not be required to transfer to Arcutis any Licensed Know-How relating solely to the chemical structure, formulation or manufacture of Licensed Compounds (and not required for submission to Regulatory Authorities) unless or until the Option is exercised by Arcutis. From time to time during the Option Period, or promptly upon Arcutis's each of reasonable requests. Hengrui shall without charge transfer any additional Licensed Know-How in Hengrui's possession (other than Licensed Know-How relating solely to the chemical structure, formulation or manufacture of Licensed Compounds and not required for submission to Regulatory Authorities) to the extent not previously delivered. Any Licensed Know-How that is required for submission to Regulatory Authorities and that was originally created in Chinese but translated to English will be delivered in both the original Chinese and translated English, along with (i) a verification that the translation is complete and accurate, and (ii) the name, address, and a brief statement of the qualifications of the person making the translation.

2.3 Option Period Supply. Subject to the terms and conditions of the Material Transfer Agreement ("***MTA***") dated January 2, 2018 by and between Hengrui and Arcutis, during the Option Period, Hengrui shall supply to Arcutis Licensed Compound in quantities at [***], at places and times, and informs, as shall be reasonably agreed between the Parties, and otherwise as may be reasonably required for Arcutis to conduct the Option Period Studies (the "***Option Period Materials***"). This cost to supply is set forth in the MTA. Arcutis shall not, and

shall not cause any Affiliate, service providers, collaborators or Third Parties to, use or transfer any Option Period Materials for any purpose other than to conduct the Option Period Studies. In addition, Arcutis may not, and may not cause any Affiliate, service providers, collaborators or Third Parties to, reverse engineer, copy, disassemble or otherwise attempt to reconstruct any Option Period Materials.

2.4 Grant of Option and Option Period License. Hengrui hereby grants to Arcutis during the Option Period:

2.4.1 an exclusive option, exercisable in Arcutis's sole discretion at any time during the Option Period, to obtain from Hengrui the license rights described in Section 3.1 (the "Option"): and

2.4.2 a non-transferable, non-sublicensable (other than to Arcutis's Affiliates, service providers and collaborators who directly participate in the Option Period Studies), fully-paid, royalty-free license under the Licensed Technology to perform the Option Period Studies as contemplated herein (the "***Option Period License***").

2.5 Option Period Studies. During the Option Period, Arcutis will design, control, and conduct those Option Period Studies deemed appropriate by Arcutis in its discretion. Arcutis shall exert Commercially Reasonable Efforts to conduct the POC Study and to complete it and the analysis of it within [***] following the Effective Date, which timeframe may be extended by Arcutis with the written consent of Hengrui (such consent not to be unreasonably withheld or delayed). During this [***] period, Arcutis will promptly notify Hengrui in writing if it is evaluating other chemical compound or compounds specifically designed for, or otherwise useful for, JAK1//2.3 (Janus kinase 1/13) inhibition, that are not Controlled by Hengrui.

2.6 Option Exercise. In the event Arcutis elects to exercise the Option, it shall prior to 11:59pm Pacific time on the last day of the Option Period, (i) deliver to Hengrui a written notice specifying that Arcutis has elected to exercise the Option ("***Option Notice***"), and (ii) pay to Hengrui a non-refundable, non-creditable fee of One Million Five Hundred Thousand Dollars ($1,500,000) (the "***Option Exercise Payment***"). The date, if any, on which Arcutis has exercised the Option by having fulfilled both (i) and (ii) in the preceding sentence, shall be the "***License Effective Date***."

2.7 Expiration and Termination of the Option Period. The Option, the Option Period, and the Option Period License will expire if the Option is not exercised on or prior to the last day of the Option Period. Arcutis may earlier terminate the Option Period at any time and for any reason, effective upon written notice to Hengrui.

2.8 Effect of Expiration or Termination of the Option Period. Upon expiration or termination of the Option Period, other than due to the occurrence of the License Effective Date. (1) the Option Period License immediately terminates and all rights associated with Licensed Technology automatically revert back to Hengrui, without requiring any act on either Party, and (2) Arcutis shall (a) immediately cease all work on the Option Period Studies, and (b) within thirty (30) days of such expiration or termination, (i) deliver to Hengrui the Option Period Study Results in writing or computer-readable form and any remaining Option Study Materials; and (ii) return or destroy, at Hengrui's choice, any physical embodiments of the Licensed Know-How provided to it by Hengrui.

ARTICLE III
LICENSES

3.1 Licenses to Arcutis.

3.1.1 Hengrui hereby grants to Arcutis, effective as of the License Effective Date, a royalty-bearing license, with the right to sublicense (through multiple tiers) as set forth in Section 3.4, under the Licensed Technology to Exploit Licensed Products in the Field in the Territory during the Term. The foregoing license shall be sole and exclusive (including as to Hengrui and its Affiliates) with respect to the Licensed Patent Rights and non-exclusive with respect to the Licensed Know-How.

3.1.2 Hengrui will make available to Arcutis for its review all future Patent Rights Controlled by Hengrui in the Territory that are improvements to a Licensed Compound or otherwise reasonably useful for the Exploitation of Licensed Products ("Improvements"), subject to any preexisting rights of Third Parties and for a limited period of six (6) months from the date of disclosure by Hengrui to Arcutis of such Improvements. Arcutis will have no rights to Exploit the Improvements under this Agreement, unless and until a mutually agreeable license agreement or one or more mutually agreeable amendments to this Agreement specifying the terms and conditions of such Exploitation is executed by the Parties.

3.2 Licenses to Hengrui. Arcutis hereby grants to Hengrui (i) a non-exclusive, non-sublicenseable (other than to Hengrui's Affiliates, service providers and collaborators), royalty-free license to use the Option Period Study Results for internal research purposes (except in the Field in the Territory), and (ii) if Arcutis exercises the Option as set forth in Section 2.1, a nonexclusive, royalty-free license with the right to sublicense (through multiple tiers) as set forth in Section 3.5, effective as of the License Effective Date, to use (except in the Field in the Territory) the Option Period Study Results and Patent Right(s) arising from the performance of the Option Period Studies that are Controlled by Arcutis.

3.3 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

3.4 Sublicensing by Arcutis.

3.4.1 Arcutis shall have the right to grant sublicenses (including any option to obtain a sublicense, each a "***Sublicense***") to any of its Affiliates or any Third Party (each, a "***Sublicensee***"), under the license set forth in Section 3.1, provided that: (a) each Sublicense shall be granted pursuant to a written agreement that complies with Section 3.4.2; (b) Arcutis shall provide Hengrui with written notice of the identity of each Sublicensee within thirty (30) days following the execution of each Sublicense, along with a redacted copy of the applicable Sublicense agreement sufficient to demonstrate compliance with clause (a); and (c) Arcutis shall remain responsible for the Sublicensee's conformity to those portions of this Agreement applicable to such Sublicensee.

3.4.2 Arcutis shall include in each such Sublicense agreement provisions that (a) such Sublicensee is bound by and subject to all applicable terms and conditions of this Agreement (other than terms and obligations bearing on financial considerations and audit rights) in the same manner and to the same extent as Arcutis's bound thereby; (b) Arcutis shall have the right to grant to Hengrui cross-reference rights consistent with Section 4.1.3(a) with respect to Regulatory Filings and Regulatory Approvals generated, filed or obtained by or on behalf of such Sublicensee within the scope of such sublicense or option agreement; (c) the Sublicensee has obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Section 9.2 hereof; and (d) the Sublicensee has indemnification obligations that are substantially the same as those undertaken by Arcutis pursuant to Section 10.3 hereof.

3.5 Sublicensing by Hengrui.

3.5.1 Hengrui shall have the right to grant Sublicenses under the license set forth in Section 3.2, provided that: (a) each Sublicense shall be granted pursuant to a written agreement that complies with Section 3.5.2;(b) Hengrui shall provide Arcutis with written notice of the identity of each Sublicensee within thirty (30) days following the execution of each Sublicense, along with a redacted copy of the applicable Sublicense agreement sufficient to demonstrate compliance with clause (a): and (c) Hengrui shall remain responsible for the Sublicensee's conformity to those portions of this Agreement applicable to such Sublicensee.

3.5.2 Hengrui shall include in each such Sublicense agreement with respect to each of the licenses under clause (i) and/or clause (ii) of Section 3.2 provisions that (a) such Sublicensee is bound by and subject to all applicable terms and conditions of this Agreement (other than terms and obligations bearing on financial considerations and audit rights) in the same manner and to the same extent as Hengrui is bound thereby; (b) Hengrui shall have the right to grant to Arcutis cross-reference rights consistent with Section 4.1.3(b) with respect to Regulatory Filings and Regulatory Approvals generated, filed or obtained within the scope of such sublicense or option agreement: (c) Hengrui shall have the right to grant to Arcutis a limited license, in the Field and in the Territory only, consistent with Section 3.1 to any and all scientific or technical information, results, materials. and data, whether or not patentable, and Patent Rights developed within the scope of such sublicense or option agreement, solely to the extent that each of the foregoing is an improvement to a Licensed Compound or otherwise reasonably useful for the Exploitation of Licensed Products, (d) the Sublicensee has obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Section 9.2 hereof, and (e) the Sublicensee has indemnification obligations that are substantially the same as those undertaken by Hengrui pursuant to Section 10.3 hereof.

3.6 Subcontractors. Arcutis may Exploit its rights in the Licensed Technology under this Agreement through one or more Third Party contractors or consultants without meeting the requirements of Section 3.4, provided that (a) Arcutis remains responsible for the performance of such activities by such contractors and consultants, and (b) the contractor or consultant undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Section 9.2 hereof.

3.7 Transfer of Licensed Know-How. After the License Effective Date, upon Arcutis's requests, Hengrui shall without charge deliver to Arcutis, in English, all additional existing Licensed Know-How not delivered during the Option Period pursuant to Section 2.2, including (a) all technical data and information within Hengrui's possession that may be required by any Regulatory Authorities in the Territory to initiate an investigational new drug file or dossier (such as an IND, IMPD, or the equivalent); and (b) all existing Licensed Know-How relating to the chemical structure, formulation or manufacture of Licensed Compounds. Any Licensed Know-How that is required for submission to Regulatory Authorities and that was originally created in Chinese but translated to English will be delivered in both the original Chinese and translated English. along with (i) a verification that the translation is complete and accurate, and (ii) the name, address, and a brief statement of the qualifications of the person making the translation. From time to time during the Term, or promptly upon Arcutis's reasonable request, Hengrui shall without charge transfer any additional Licensed Know-How in Hengrui's possession to the extent not previously delivered.

ARTICLE IV
DEVELOPMENT, COMMERCIALIZATION, NON-COMPETITION

4.1 Development.

4.1.1 Pre-Clinical and Clinical Activities. From and after the License Effective Date, as between the Parties, Arcutis shall have sole responsibility for the Exploitation of one or more Licensed Products in the Field in the Territory at its cost and expense (including responsibility for all funding, resourcing and decision-making).

4.1.2 Regulatory Filings. As between Arcutis and Hengrui, Arcutis will have sole responsibility for (a) preparing and submitting all Regulatory Materials for Licensed Products in the Field in the Territory and (b) determining all regulatory plans and strategies for Licensed Products in the Field in the Territory. As between the Parties, Arcutis will have the exclusive right to submit to and appear before Regulatory Authorities on any matter with respect to Licensed Products in the Field in the Territory. Arcutis (or its Affiliates or Sublicensees, as applicable) will own all Regulatory Materials (including Regulatory Approvals) for Licensed Products in the Field in the Territory and all such Regulatory Materials shall be submitted in the name of Arcutis (or its Affiliate or Sublicensee, as applicable) in the Field in the Territory. As between the Parties. Arcutis shall have sole decision-making authority for all regulatory matters with respect to Licensed Products in the Field (including the content of any regulatory filing or dossier, pharmacovigilance reports, patient risk management strategies and plans, labeling, safety, the decision to file any MAA, and recalls and withdrawals) in the Territory.

4.1.3 Mutual Cross-Reference Rights. From and after the Licensed Effective Date:

(a) Arcutis will provide Hengrui with any appropriate letters or other similar documentation necessary to authorize Hengrui, its licensees (subject to 9.1.2(i)) and Sublicensees (subject to 3.5.2(b)) to cross-reference and rely (on a non-exclusive basis) upon the contents of any of Regulatory Filings and Regulatory Approvals for the Licensed Products in the Field in the Territory, for the purposes of the filing, obtaining and maintaining of Regulatory Approvals for Licensed Products (except in the Field in the Territory).

(b) Hengrui will provide Arcutis with any appropriate letters or other similar documentation necessary to authorize such Arcutis and its Sublicensees (subject to 3.4.2(b)) to cross-reference and rely (on a non-exclusive basis) upon the contents of any of Regulatory Filings and Regulatory Approvals for the Licensed Products, for the purposes of the filing, obtaining and maintaining of Regulatory Approvals for Licensed Products in the Field in the Territory.

4.1.4 Development Reports. Within sixty (60) days of January 1 of a Calendar Year, Arcutis will provide to Hengrui a high-level annual written report presenting a summary of the development and regulatory activities of Arcutis with respect to Licensed Products in the Field in the Territory (each, a "***Development Report***"). Such reports and the contents thereof shall be Confidential Information of Arcutis.

4.1.5 Support. Upon Arcutis's request, Hengrui shall (a) provide reasonable assistance, at Arcutis's cost and expense (at Hengrui's ordinary FTE rate) to support the Arcutis's activities under this Section 4.1, including with respect to writing and finalizing any reports necessary to support the filing of an IND with the FDA for the Licensed Product selected.

4.1.6 Timeline. Arcutis agrees, under good faith and Commercially Reasonable Efforts, to develop at least one (1) Licensed Product. If the pace of clinical development of Licensed Product appears unusually slow or challenging, Hengrui and Arcutis agree to meet to review the status of such development. The Parties acknowledge that breach of this Section 4.1.6 is material breach for the purpose of Section 11.2.

4.2 Commercialization.

4.2.1 Marketing and Commercialization Activities. Upon receiving Regulatory Approval for one or more Licensed Product(s) in one or more country(ies) of the Territory, Arcutis will have sole right and responsibility with respect to the marketing and commercialization of such Licensed Product(s) in such country(ies).

4.2.2 Commercialization Report. For each Calendar Year following first Regulatory Approval for a Licensed Product, Arcutis shall provide to Hengrui annually within sixty (60) days after the end of such Calendar Year a high-level report summarizing Arcutis's activities with respect to the commercialization of Licensed Products in the Field in the Territory in such Calendar Year ("***Commercialization Report***). Such reports and the contents thereof shall be Confidential Information of Arcutis.

4.2.3 Timeline. Arcutis agrees that, following Regulatory Approval of a licensed Product, it will use good faith and Commercially Reasonable Efforts to commercialize such Licensed Product. lithe pace of commercialization of Licensed Product appears unusually slow or challenging, Hengrui and Arcutis agree to meet to review the status of such commercialization. The Parties acknowledge that breach of this Section 4.2.3 is material breach for the purpose of Section 11.2.

4.3 Joint Coordination Committee

(a) Establishment. Within sixty (60) days after the Effective Date, the Parties shall establish a joint coordination committee ("***Joint Coordination Committee***" or the "***JCC***") to (i) review Arcutis's Development and commercialization of Licensed Products in the Field in the Territory, (ii) review Hengrui's Development and commercialization of Licensed Products outside of the Field and/or outside of the Territory and (iii) in the event that both Parties are Developing and/or commercializing the same Licensed Product, coordinate the activities of the Parties with respect to such Licensed Product, including safety data and registration in the respective field and territory; (iv) facilitate communication with respect to each Party's activities under this Agreement; and (v) perform such other functions as are specifically designated for the JCC in this Agreement or otherwise as agreed by the Parties.

(b) Committee Membership. The JCC shall each be comprised of an equal number of representatives from each Party. Unless otherwise agreed by the Parties, the exact number of such representatives for each of Arcutis and Hengrui shall be three (3). Either Party may replace its respective representatives at any time with prior notice to the other Party, provided that, such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing.

(c) Meetings. The JCC shall each meet at least two (2) times during each year, or as more or less often as otherwise agreed by the Parties, and such meeting may be conducted by telephone, videoconference or in person as determined by the JCC; provided that at least one meeting per year shall be held in person. All in-person meetings shall be held on an alternating basis between Arcutis's and Hengrui's facilities, unless otherwise agreed by the Parties. As appropriate, other employee representatives of the Parties may attend Committee meetings as observers, but no Third-Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings to resolve particular matters requested by such Party.

(d) Scope of Governance. The JCC shall not have any decision making authority, and each Party shall retain the rights, powers and discretion to decide matters concerning the Development and commercialization of Licensed Products in its respective field and territory, provided that such decisions are consistent with the terms and conditions of this Agreement. In no event shall the JCC be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein. or the Parties expressly so agree in writing.

4.4 Non-Competition

4.4.1 Non-competition by Arcutis, During the Option Period, and continuing during the Term after exercise of the Option by Arcutis, if Arcutis acquires rights in, develops, or causes the development of a ligand that binds to Janus Kinase (JAK) I, JAK2 and/or JAK3 in the Field. to the extent such ligand is not Controlled by Hengrui ("***Competing Product***"). Arcutis shall immediately notify Hengrui by writing, and the Parties shall negotiate in good faith whether, in each case as mutually agreed upon:

(a) to terminate all rights and licenses granted under this Agreement, or

(b) to grant to Hengrui a license or sublicense, as the case may be, the right to develop and commercialize the Competing Product in China.

Notwithstanding the foregoing, in the event Arcutis undergoes a Change of Control (as defined in Section 5.3.5), then this Section 4.4.1 shall not apply to any program for the research, development and/or commercialization of a Competing Product that the Third Party acquiror (and/or its Affiliates existing immediately prior to the consummation of such Change of Control) had ongoing immediately prior to the consummation of such Change of Control (each such program, a "***Competing Program***"), provided that (i) no Licensed Technology is used by the acquiror in connection with such Competing Program(s), and (ii) the acquiror segregates the personnel engaged in the research, development and/or commercialization of the Licensed Compound and any Licensed Product from the personnel engaged in the Competing Program(s).

4.4.2 Non-competition by Hengrui.

(a) During the Option Period and continuing during the Term after exercise of the Option by Arcutis, Hengrui shall not develop or commercialize the Licensed Compound or any Licensed Product in the Field in the Territory.

(b) During the Option Period and continuing during the Term after exercise of the Option by Arcutis, if Hengrui decides to grant a license or other rights with respect to the License Compound or any Licensed Product in the Additional Field anywhere in the Territory, Arcutis shall have the right of first refusal for such license or other rights as set forth in this subclasses (b). Prior to granting any such license or other rights to any Third Party, Hengrui shall provide Arcutis written notice ("***Hengrui ROFR Notice***"), which shall identify the rights that Hengrui wishes to grant to such Third Party and the associated financial and other material terms. If, within thirty (30) days following receipt of the Hengrui ROFR Notice, Arcutis notifies Hengrui of its interest to obtain such rights, Hengrui and Arcutis shall negotiate in good faith for a period of ninety (90) days an amendment to this Agreement to incorporate such rights. If (a) Arcutis does not provide such written notice within thirty '30) days or (b) the Parties fail execute such amendment within ninety (90) days following Arcutis's written notification, then Hengrui shall be free to grant such rights to such Third Party on terms that are no more favorable 'when taken as a whole) to such Third Party than those last offered to Arcutis and otherwise shall have no further obligation to Arcutis. "***Additional Field***" means non-topical formulation's) of Licensed Compound indicated for the treatment of psoriasis, vitiligo, atopic dermatitis, alopecia areata, and. or hidradenitis suppurativa.

(c) [***]

ARTICLE V
PAYMENTS

5.1 Milestone Payments. Arcutis shall pay to Hengrui the respective one-time only (for clarity, in each case only for the first Licensed Product), non-refundable milestone payments set forth below upon the first achievement of the applicable milestone event.

Milestone Event	Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

5.2 Milestone Payment Terms. Arcutis shall notify Hengrui in writing within fifteen (15) Business Days following the achievement of each milestone event set forth in Section 5.1, and, except as noted below, shall make the appropriate milestone payment in Dollars by wire transfer to a bank designated in writing by Hengrui, within sixty (60) days after the achievement of such milestone event. Each milestone payment stated in the table in Section 5.1 shall be paid no more than once under this Agreement, regardless of whether or not similar achievements) are thereafter made for the same or one or more other Licensed Products. [***]

5.3 Royalties.

5.3.1 Royalty Payments. Arcutis shall pay to Hengrui royalties, with respect to Net Sales, at the following royalty rates:

Portion of Aggregate Net Sales during a Calendar Year	Royalty Rate, as of that Portion of Net Sales
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

5.3.2 Step-Down. The royalty rates under Section 5.3.1 shall be reduced, on a country-by-country basis, to [***] of the rates otherwise stated in Section 5.3.1 with respect to any Net Sales made during any portion of the Royalty Term in the country of sale in which there is not at least one (1) Valid Claim under Licensed Patent Rights in such country.

5.3.3 Anti-Stacking. [***]

5.3.4 Generic Competition. Upon commencement of Generic Competition with respect to a Licensed Product in a country within the Territory, and thereafter for so long as such Generic Competition persists, the royalty rates applicable under Section 5.3.1 shall [***].

5.3.5 Sublicensing Income. During the Term, Arcutis shall pay Hengrui a portion of any and all non-royalty sublicense income received by Arcutis in consideration for a Sublicense under the license set forth in Section 3.1, including upfront and milestone payments ("Sublicensing Income") (each such payment to be made within sixty (60) days of Arcutis's receipt of the applicable Sublicensing Income), according to the following schedule:

Stage of development of License Product reached by Licensee, Sublicensee or Affiliate in Territory	Percent of Sublicensing Income due to Hengrui
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]

For the purposes of this Section 5.3.5. sublicensing income will not include anything of value Arcutis receives as part clan) transaction relating to a change of control ("***Change of Control***"). A Change of Control means an occurrence any of the following:

(a) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of Arcutis representing more than 50% of the total voting power represented by Arcutis's then outstanding voting securities; or

(b) The consummation of the sale or disposition by Arcutis all or substantially all of its assets; or

(c) The consummation of a merger or consolidation of Arcutis with any other corporation, other than a merger or consolidation which would result in the voting securities of Arcutis's outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least 50% of the total voting power represented by the voting securities of Arcutis or such surviving entity or its parent outstanding immediately after such merger or consolidation.

5.3.6 Payment Terms. Royalties reportable in each Royalty Report provided for under Section 6.1 shall be due on the date such Royalty Report is due. Royalty payments will be made to Hengrui in Dollars by wire transfer to a bank designated in writing by Hengrui.

5.4 Taxes. Payment shall be made in full, without deduction or withholding for currency exchange fees. Arcutis and Hengrui shall equally split any wire transfer fees. Hengrui shall pay all sales, turnover, income, revenue, value added, and other taxes, levies, and governmental charges ("***Taxes***") levied on account of any milestone and royalty payments accruing or made to Hengrui under this Agreement. If and to the extent that provision is made in law or regulation of any country for withholding of Taxes with respect to any such payment, then Arcutis shall promptly pay such Tax for and on behalf of Hengrui to the proper Governmental Authority, and shall promptly furnish Hengrui with receipt of payment. Arcutis shall be entitled to deduct any such Taxes actually paid from such milestone or other payment due Hengrui, or be promptly reimbursed by Hengrui if no further payments are due to Hengrui. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreements or treaties from time to time in force and in minimizing the amount required to be so withheld or deducted.

ARTICLE VI
ACCOUNTING AND REPORTING

6.1 Royalty Reports. Within [***] after the end of each Calendar Quarter during the term of this Agreement following the First Commercial Sale of a Licensed Product, Arcutis shall furnish to Hengrui a quarterly written report showing in reasonably specific detail (a) the calculation of Net Sales by Arcutis and its Affiliates during such Calendar Quarter; (b) the calculation of Net Sales by Arcutis's non-Affiliate Sublicensees, if during the Calendar Quarter immediately preceding such Calendar Quarter; (c) the calculation of the royalties, if any, that shall have accrued based upon such Net Sales; (d) the withholding taxes. if any, required by law to be deducted with respect to such sales; and (e) the exchange rates, if any, used in determining the amount of Dollars 'a "***Royalty Report***"). With respect to sales of Licensed Products invoiced in Dollars, the gross sales, Net Sales and royalties payable shall be expressed in Dollars. With respect to (i) Net Sales invoiced in a currency other than Dollars and (ii) cash consideration paid in a currency other than Dollars by Sublicensees hereunder, all such amounts shall be expressed both in the currency in which the distribution is invoiced and in the Dollar equivalent. The Dollar equivalent shall be calculated using the average of the exchange rate (local currency per US $1) published in The Wall Street Journal, Western Edition, under the heading ''Currency Trading" on the last business day of each month during the applicable Calendar Quarter, or other newspaper agreed to by the Parties.

6.2 Audits. During the Royalty Term, upon the written request of Hengrui and not more than once in each Calendar Year, Arcutis shall permit an independent certified public accounting firm of nationally recognized standing selected by Hengrui and reasonably acceptable to Arcutis, at Hengrui's expense, to have access during normal business hours to such of the financial records of Arcutis as may be reasonably necessary to verify the accuracy of the payment reports hereunder for the eight (8) Calendar Quarters immediately prior to the date of such request (other than records for which Hengrui has already conducted an audit under this Section).

6.2.1 If such accounting firm concludes that additional amounts were owed during the audited period, Arcutis shall pay such additional amounts within thirty (30) days after the date Hengrui delivers to Arcutis such accounting fires written report so concluding. The fees charged by such accounting firm shall be paid by Hengrui; provided, however, if the audit discloses that the royalties payable by Arcutis for such period are more than [***] of the royalties actually paid for such period, then Arcutis shall pay the reasonable fees and expenses charged by such accounting firm.

6.2.2 Hengrui shall cause its accounting firm to retain all financial information subject to review under this Section 6.2 in strict confidence; provided, however, that Arcutis shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Arcutis regarding such financial information. The accounting firm shall disclose to Hengrui only whether the reports are correct or not and the amount of any discrepancy. No other information shall be shared. Hengrui shall treat all such financial information as Arcutis's Confidential Information.

ARTICLE VII
INTELLECTUAL PROPERTIES

7.1 Ownership.

7.1.1 Background Technologies. Other than Option Period Study Results, each Party shall retain all rights, title and interest in and to its respective background technologies and intellectual properties (collectively. the "***Background Technologies***"), including patents, patent applications, rights to patents, confidential information, know-how, programs, and processes in existence prior to the Effective Date or conceived, developed or acquired thereafter. Except for the licenses and rights expressly set forth in this Agreement, neither Party grants or shall be required to grant to the other Party, by implication or otherwise, any license or right under its Background Technologies, nor will a Party be required to disclose any of its Background Technologies to the other Party, except as is explicitly required under this Agreement. For clarity, any Invention, scientific or technical information, results, materials, and data conceived, developed or acquired during the Term, other than Option Period Study Results, shall be part of the Background Technologies, and ownership thereof shall be as determined under the inventorship and authorship rules and precedents prevailing in the United States.

7.1.2 Option Period Study Results. Should any Invention, scientific or technical information, results, materials, and data, whether or not patentable, be conceived, developed or acquired directly in the course of work done in the Option Period Studies, it and all intellectual property and other rights and title therein, including patents, patent applications, rights to patents, confidential information, know-how, programs, and processes (a) shall be owned by Arcutis to the extent the same was conceived, developed or acquired solely by Arcutis

or its personnel; (b) shall be owned by Hengrui to the extent the same was conceived, developed or acquired solely by Hengrui or its personnel; and (c) shall be jointly owned by both Parties if it was conceived, developed or acquired jointly by both Parties or their respective personnel. Inventorship and authorship will be determined under the applicable rules and precedents prevailing in the United States. For clarity, any Option Period Study Results solely or jointly owned by Hengrui shall, to the extent of such interest, be part oldie Licensed Know-How or Licensed Patents, as the case may be.

7.1.3 Rights of Joint Owners. Subject to the licenses and covenants in this Agreement, including Sections 3.1, 3.2, and 9.1, each of the joint owners of any Option Period Study Results or jointly-owned Background Technologies (if any)shall be entitled during and after the Term to make, use, sell, offer for sale, import, reproduce, modify ‘and make derivative works from), distribute, perform, display and otherwise exploit and practice any such jointly-owned Option Period Study Results or jointly-owned Background Technologies (if any) and to authorize others to do so, without requirement of consent from or accounting to the other owner of such intellectual property. Nothing in this Section 7.1.3 should be construed as granting any license, implied or express, other than the licenses expressly granted under this Agreement.

7.2 Patent Prosecution and Maintenance.

7.2.1 Hengrui shall Prosecute all Licensed Patent Rights owned solely by Hengrui or jointly by Hengrui and a Third Party in its sole discretion and at its own cost and using prosecution counsel of its choice. Hengrui shall promptly provide to Arcutis copies of all material prosecution communications regarding any such Licensed Patent Rights in the Territory, and will send Arcutis copies of drafts of such material prosecution submissions prior to filing. Hengrui will specifically consider all comments and suggestions provided by Arcutis on such material patent prosecution submissions in good faith and will use reasonable efforts to arrive at joint decisions on responses. If Hengrui decides to abandon or terminate any such Licensed Patent Rights in the Territory, it shall provide written notice to Arcutis no less than thirty (30) days prior to termination and give Arcutis the opportunity to take over, at Arcutis’s expense, the prosecution and maintenance of such Patent Rights.

7.2.2 Arcutis shall Prosecute all Patent Rights owned solely by Arcutis or jointly by Arcutis and a Third Party in its sole discretion and at its own cost and using prosecution counsel of its choice.

7.2.3 The Parties shall cooperate in good faith to determine which Party or Parties shall Prosecute Patent Rights owned jointly by Hengrui and Arcutis.

7.3 Enforcement of Patent Rights.

7.3.1 Notice of Infringement. Each Party shall promptly inform the other of any suspected infringement of any of the Licensed Patent Rights or the infringement or misappropriation of Licensed Know-How by a Third Party, to the extent such infringement involves Exploitation in the Field during the Term. Any suspected infringement of any of the Licensed Patent Rights in the Field in the Territory is referred to herein as a “***Covered Infringement.***”

7.3.2 First Right to Take Action. If a suspected infringement or misappropriation does not involve a Covered Infringement, Hengrui may take, or refrain from taking, any action Hengrui chooses, and Arcutis shall have no right to take any action with respect to such suspected infringement or misappropriation, nor to any recoveries with respect thereto. Hengrui will exert reasonable efforts to keep Arcutis informed of actions Hengrui may take as described in the preceding sentence. If the suspected infringement involves a Covered Infringement, Arcutis shall, within thirty (30) days of the first notice referred to in Section 7.3.1, inform Hengrui whether or not Arcutis (and/or its Sublicensee) intends to institute suit against such Third Party with respect to such Covered Infringement. Hengrui will not take any steps toward instituting suit against any Third Party involving a Covered Infringement until Arcutis has informed Hengrui of its intention pursuant to the previous sentence.

7.3.3 Action by Arcutis. If Arcutis notifies Hengrui that Arcutis (and/or its Sublicensee) intends to institute suit against a Third Party with respect to a Covered Infringement, and Hengrui does not agree to join in such suit as provided in Section 7.3.4, Arcutis (and/or its Sublicensee) may bring such suit on its own and shall in such event bear all costs of, and shall exercise all control over, such suit. Arcutis (and/or its Sublicensee) may, at its expense, bring such action in the name of Hengrui and/or cause Hengrui to be joined in the suit as a plaintiff. Recoveries, if any, whether by judgment, award, decree or settlement, shall, after reimbursement of Arcutis for the costs of such action, be treated as if they were Net Sales for purposes of calculating royalties under Section 5.3.

7.3.4 Joint Action. If Arcutis notifies Hengrui that it (and/or its Sublicensee) desires to institute suit against such Third Party with respect to a Covered Infringement, and Hengrui notifies Arcutis within thirty (30) days after receipt of such notice that Hengrui desires to institute suit jointly, the suit shall be brought jointly in the names of both Parties and all costs thereof shall be borne equally. Recoveries, if any, whether by judgment, award, decree or settlement, shall, after the reimbursement of each of Hengrui and Arcutis for its share of the joint costs in such action, be shared in relation to the damages suffered by each Party.

7.3.5 Action by Hengrui. If Arcutis notifies Hengrui that it (and or its Sublicensee) does not intend to institute suit against such Third Party with respect to a Covered Infringement (or fails to give any notice in this respect or to actually bring a suit against the Third Party). Hengrui may institute suit on its own. Hengrui shall bear all costs of, and shall exercise all control over, such suit. Recoveries, if any, whether by judgment, award, decree or settlement, shall belong solely to Hengrui.

7.3.6 Abandonment of Actions. Should either Hengrui or Arcutis (and/or its Sublicensee) commence a suit under the provisions of this Section 7.3 and thereafter elect to abandon the same, it shall give timely notice to the other Party, who may, if it so desires, be joined as a plaintiff in the suit (or continue as such if it is already one) and continue prosecution of such suit, provided, however, that the sharing of expenses and any recovery of such suit shall be as equitably agreed upon between Hengrui and Arcutis.

7.3.7 Cooperation. In any suit to enforce and/or defend the Licensed Patent Rights pursuant to this Section 7.3, the Party not in control of such suit shall, at the request and expense of the controlling Party, reasonably cooperate and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

ARTICLE VIII
REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

8.1.1 Such Party is a corporation duly organized, validly existing and in good standing under the laws of the State or country in which it is incorporated.

8.1.2 Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

8.1.3 All necessary consents, approvals and authorizations of all Governmental Authorities and other persons required to be obtained by such Party in connection with this Agreement have been obtained.

8.1.4 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law and (b) do not conflict with, or constitute a default under, any contractual obligation of such Party.

8.2 Hengrui Additional Representations and Warranties. Hengrui hereby represents and warrants to Arcutis as follows:

8.2.1 Hengrui and its Affiliates own the Licensed Technology, and, without limiting the foregoing, Hengrui is entitled to grant the licenses specified herein with respect thereto.

8.2.2 Hengrui and its Affiliates have not granted to any Third Party any option, license or other right or interest under the Licensed Patent Rights to Exploit the Licensed Technology in the Field in the Territory as of the Effective Date and during the Term of this Agreement, unless this Agreement is earlier terminated or the Option is not exercised on or prior to the last day of the Option Period, Hengrui will not grant to any Third Party any option, license or other right or interest under the Licensed Patent Rights to Exploit the Licensed Technology in the Field in the Territory.

8.2.3 No employee of Hengrui or its Affiliates has breached any non-use or confidentiality obligations under any agreement with his or her respective prior employers, or has otherwise misappropriated any trade secret or confidential information of such employers, in each case relating to the Licensed Technology.

8.2.4 To the best actual knowledge of Hengrui the development, use, sale and import of Licensed Compounds will not infringe or misappropriate any valid intellectual property rights owned or possessed by any Third Party.

8.2.5 To the best actual knowledge of Hengrui, there are no pending or threatened claims, judgments or settlements against Hengrui or its Affiliates relating to the Licensed Technology.

8.2.6 Hengrui has disclosed, or will disclose to Arcutis in accordance with Section 2.3, all material information in its or its Affiliates' possession regarding the Licensed Compounds (including all clinical trial and safety data, databases and analyses).

8.2.7 To the best actual knowledge of Hengrui, no Third Party has infringed or misappropriated or is infringing or misappropriating any Licensed Technology.

ARTICLE IX
COVENANTS

9.1 Exclusivity; Other Agreements.

9.1.1 During the Option Period and continuing during the Term after exercise of the Option by Arcutis, Hengrui and its Affiliates shall not, without Arcutis's prior written consent in each instance: (a) grant or assign to any Third Party any option, license or other right in the Field in the Territory under the Licensed Technology or any portion or aspect thereof, or (b) solicit or enter into or continue any negotiations or discussions with any Third Party with respect to any of the foregoing.

9.1.2 [***]

9.2 Obligations of Confidentiality and Non-Use.

9.2.1 Confidential Information. Except as expressly provided herein, the Parties agree that the receiving Party shall not publish or otherwise disclose and shall not use for any purpose any information furnished to it by the other Party hereto under this Agreement (or prior to the Effective Date) which if disclosed in tangible form is marked "Confidential" or with other similar designation to indicate its confidential or proprietary nature or if disclosed orally is indicated orally to be confidential or proprietary by the Party disclosing such information at the time of such disclosure and is confirmed in writing as confidential or proprietary by the disclosing Party within a reasonable time after such disclosure (collectively, "***Confidential Information***"). Notwithstanding the foregoing. Confidential Information shall not include information that, in each case as demonstrated by written documentation:

(a) was already known to the receiving Party at the time of first disclosure or, as shown by written documentation, was developed by the receiving Party outside the Option Period Studies and independent of disclosure by the disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

(d) was subsequently lawfully disclosed to the receiving Party by a person other than a Party or developed by the receiving Party without reference to any information or materials disclosed by the disclosing Party.

9.2.2 Permitted Disclosures. Notwithstanding the provisions of Section 9.2.1 above, each Party hereto may disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it under this Agreement, prosecute or defend litigation, prosecute patent applications in accordance with this Agreement, comply with applicable laws or governmental regulations, submit information to tax or other Governmental Authorities, provided that if a Party is required to make any such disclosure of the other Party's Confidential Information, to the extent it may legally do so, it will give reasonable advance notice to such other Party of such disclosure and. save to the extent inappropriate in the case of patent applications or otherwise. will use its reasonable efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or otherwise).

9.2.3 Terms of Agreement. Subject to Section 9.2.1, neither Party may disclose the terms of this Agreement without the prior written consent of the other Party; provided, however, that either Party may make such a disclosure (a) to the extent required by law or by the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has or has applied to have its securities listed or traded, (b) to its legal and financial advisors, or (c) to any actual or prospective acquirers, investors, collaborators and lenders (as well as and to their respective legal and financial advisors) who are obligated to keep such information confidential. If such disclosure is required under clause (a), the disclosing Party shall make reasonable efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure.

9.2.4 Publicity. Without limiting the foregoing, and except to the extent required by law or by the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has or has applied to have its securities listed or traded, neither Party shall be permitted to, directly or indirectly, issue any press release or other public statement relating to the terms of this Agreement or the transactions contemplated thereby without the prior approval of the other Party, which shall not be unreasonably withheld or delayed.

9.3 Further Assurances; Consents. Each Party shall use reasonable efforts to take such action as is reasonably necessary or appropriate in order to complete the transactions contemplated hereby on the terms and subject to the conditions set forth herein.

9.4 Transition Services. During the Option Period and thereafter, for a period of [***] from and after the License Effective Date, Hengrui agrees to provide reasonable assistance to Arcutis with respect to understanding and using the Licensed Know-How at no additional cost to Arcutis (the "**Transition Services**").

ARTICLE X
LIABILITY AND INDEMNITY

10.1 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, EXEMPLARY OR INDIRECT DAMAGES OF ANY KIND ARISING FROM OR RELATING TO ANY PERFORMANCE OR BREACH OF THIS AGREEMENT OR ANY CLAIMS ARISING HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE). REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.1 IS INTENDED TO OR WILL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 10.2. (B) DAMAGES AVAILABLE TO A PARTY

10.2 FOR A BREACH BY THE OTHER PARTY OF THE CONFIDENTIALITY OBLIGATIONS UNDER SECTION 9.2. OR (C) DAMAGES AVAILABLE IN THE CASE OF BREACH OF EXCLUSIVITY UNDER SECTIONS 3.1 AND 9.1.

10.3 Indemnification.

10.3.1 Each Party (the "***Indemnitor***") shall defend, indemnify, and hold the other Party (the "***Indemnitee***") harmless from all losses, liabilities, damages and expenses (including attorneys' fees and costs) incurred as a result of any claim, demand, action or proceeding arising out of any breach of this Agreement by the Indemnitor, or the gross negligence or willful misconduct of the Indemnitor in the performance of its obligations under this Agreement, except in each case to the extent arising from the gross negligence or willful misconduct of the Indemnitee or the breach of this Agreement by the Indemnitee.

10.3.2 Arcutis, as the Indemnitor, shall defend, Indemnify, and hold Hengrui (as the Indemnitee) harmless from all losses, liabilities, damages and expenses (including attorneys' fees and costs) incurred as a result of any claim, demand, action or proceeding arising out of the Exploitation of Licensed Products by Arcutis, its Affiliate or its Sublicensee, except in each case to the extent arising from the gross negligence or willful misconduct of any Indemnitee, or from any breach of this Agreement by Hengrui.

10.3.3 Indemnification Procedures. The Indemnitee promptly shall notify the Indemnitor of any liability or action in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the right to assume the defense thereof with counsel selected by the Indemnitor. The indemnity agreement in this Section 10.3 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve

the Indemnitor of any liability to the Indemnitee under this this Section 10.3. The Indemnitee under this Section 10.3, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or liability covered by this indemnification.

ARTICLE XI
TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "***Term***") shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article II, will continue until the end of the last-to-expire Royalty Term. Upon such expiration. Arcutis shall have, and Hengrui does hereby grant to Arcutis, an exclusive, royalty-free, fully paid-up, perpetual, non-terminable, non-revocable license, with the right to sublicense (through multiple tiers) to use the Licensed Know-How to Exploit Licensed Products in the Field in the Territory.

11.2 Termination for Breach. Each Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach to the reasonable satisfaction of the other Party within ninety (90) days after notice of such breach from the non-breaching Party; provided, however, that if the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in such notice of breach and such alleged breaching Party provides the other Party notice of such dispute within thirty (30) clays after receiving such notice, then the Party that gave the notice of breach shall not have the right to terminate this Agreement under this Section 11.2 unless and until it is determined in accordance with Section 12.2 that the alleged breaching Party has materially breached the Agreement as specified in the notice of breach, and then such breaching Party fails to cure such breach within ninety (90) days following such determination. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

11.3 Termination for Insolvency. Each Party shall have the right to terminate this Agreement upon written notice to the other Party if the other Party incurs an Insolvency Event; *provided*, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or if such proceeding is not dismissed or stayed within thirty (30) days after the filing thereof. "***Insolvency Event***" means circumstances under which a Party (i) has a receiver or similar officer appointed over all or a material part of its assets or business; (ii) passes a resolution for winding-up of all or a material part of its assets or business (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court enters an order to that effect; (iii) has entered against it an order for relief recognizing it as a debtor under any insolvency or bankruptcy laws (or any equivalent order in any jurisdiction); or (iv) enters into any composition or arrangement with its creditors with respect to all or a material part of its assets or business (other than relating to a solvent restructuring).

11.4 Termination for Convenience. Arcutis shall have the right to terminate this Agreement at any time and for any reason upon ninety (90) days prior written notice to Hengrui, after having discussed or consulted any potential cause or concern in good faith with Hengrui. In the event of termination of this Agreement under this Section 11.4: (i) Arcutis shall pay all amounts then due and owing to Hengrui as of the termination date; (ii) all rights associated with Licensed Technology, to the extent granted by Hengrui to Arcutis, automatically revert back to Hengrui as of the notice date, provided, however, that Arcutis and other Selling Parties, as applicable, shall be permitted to distribute and sell all Licensed Products that were in inventory or in production on an effective termination date for a period of twelve (12) months following the effective termination date ("***Commercialization Wind-Down Period***"). in accordance with the terms of this Agreement; and (iii) except for the surviving provisions set forth in Section 11.5.1, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination.

11.5 Effect of Expiration or Termination. Upon expiration or termination of this Agreement for any reason:

11.5.1 The Parties shall not be relieved of any obligation accruing prior to such expiration or termination, and the provisions of Article l (Definitions) (to the extent any of the terms defined therein are used in any or the provisions surviving pursuant to this Section 11.5.1), Section 3.3 (No Other Licenses), Article 5 (Payment) (limited to payments that remain due and owing to Hengrui at the time of such expiration or termination). Sections 6.2 (Audits), 7.1 (Ownership). 7.2 (Patent Prosecution and Maintenance) and 7.3 (Enforcement of Patent Rights) (limited to suits that are pending as of the time of such expiration or termination). Article 8 (Representations and Warranties), Sections 9.2 (Obligations of Confidentiality and Non-Use), 11.1 (Term) (with respect to the second sentence), 11.4 (Termination for Convenience) (with respect to the second sentence), and 11.5 (Effect of Expiration or Termination), and Article 12 (General Provisions) shall survive the expiration or termination of this Agreement.

11.5.2 To the extent the Agreement is only partially terminated, the licenses granted to Arcutis in Section 3.1 shall terminate solely with respect to the Licensed Compound(s), Licensed Product(s) and country(ies) in which the termination becomes effective; provided, however, that Arcutis and other Selling Parties, as applicable, shall be permitted to distribute and sell all Licensed Products that were in inventory or in production on an effective termination date during the Commercialization Wind-Down Period, in accordance with the terms of this Agreement.

11.5.3 Notwithstanding the foregoing, no termination of this Agreement shall be construed as a termination of any Sublicense any Sublicensee hereunder, and thereafter:

(a) each such Sublicensee of Arcutis or of any of its Sublicensees in any tier shall be considered a direct licensee of Hengrui, provided that (i) Arcutis has first represented and warranted to Hengrui that, to Arcutis's actual knowledge, as of the effective date of such termination, such Sublicensee is then in full compliance with all terms and conditions of its sublicense, and (ii) such Sublicensee agrees inwriting to assume all applicable obligations of Arcutis under this Agreement; and

(b) each such Sublicensee of Hengrui or of any of its Sublicensees in any tier shall be considered a direct licensee of Arcutis, provided that (i) Hengrui has first represented and warranted to Arcutis that, to Hengrui's actual knowledge, as of the effective date of such termination, such Sublicensee is then in full compliance with all terms and conditions of its sublicense, and (ii) such Sublicensee agrees inwriting to assume all applicable obligations of Hengrui under this Agreement.

11.5.4 Except where inconsistent with any Sublicense that is to survive termination pursuant to Section 11.5.3 above, and subject to Sections 3.3 and 11.5.5, Hengrui shall have the right to Exploit Licensed Products itself or with one or more Third Parties in the Field in the Territory, and shall have the right, without obligation to Arcutis, to take any such actions in connection with such activities as Hengrui (or its designee), at its discretion, deems appropriate.

11.5.5 Except in the case of termination by reason of Hengrui's breach. Arcutis agrees to grant and hereby grants to Hengrui the option, exercisable within sixty (60) days of the effective date of termination or expiration of the Term to negotiate an exclusive or nonexclusive, royalty-bearing license to all or part of Arcutis's Background Technology, if any, in existence on such effective date of termination or expiration and required for Hengrui's Exploitation in the Field in the Territory of those Licensed Products (if any) that were under development, or being commercialized by Arcutis or its Affiliate or Sublicense in the Field in the Territory as of or within ninety (90) clays prior to such effective date of termination or expiration. such license to cover the right to do the foregoing under such Background Technology (the "***Hengrui Option***"). Hengrui may exercise the Hengrui Option by providing written notice to Arcutis of exercise of the Hengrui Option and describing the Background Technology it wishes to license. In such case, the Parties will negotiate in good faith the terms of such a license. In the event the Parties are unable to agree upon such terms within sixty (60) days, neither Party will be obligated to enter into such a license with the other.

ARTICLE XII
GENERAL PROVISIONS

12.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

12.2 Dispute Resolution. The Parties shall meet and discuss in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties do not fully settle any dispute, controversy or claim arising out of or relating to this Agreement, its negotiations, execution or interpretation, or the performance by either Party of its obligations under this Agreement (other than (a) any Patent Controversy, or (b) any bona fide Third Party action or proceeding filed or instituted in an action or proceeding by a Third Party against a Party to this Agreement), whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give prompt written notice to that effect to the other Party. Any such arbitration shall be conducted in the English language under the International Dispute Resolution Procedures and Arbitration Rules of the American Arbitration Association (the "***Rules***") by a panel of three (3) arbitrators appointed in accordance with such

Rules. Any such arbitration shall be held in Hong Kong. The method and manner of discovery in any such arbitration proceedings shall be governed by the Rules. The arbitrators shall have the authority to grant specific performance and to allocate between the Parties the costs of arbitration (including attorneys' fees and expenses of the Parties) in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute. controversy or claim hereunder.

12.3 Patent Controversies. Notwithstanding anything in this Agreement to the contrary, any Patent Controversy shall be subject to adjudication in accordance with the Applicable Laws of the country or jurisdiction in which the relevant Patent Right is pending or has been issued. The Parties agree that the venue of any such adjudication involving a Patent Right pending in or issued by the United States shall be a U.S. Federal District Court (or appellate body, as necessary) sitting in San Francisco, California. U.S.A. and for a Patent Right pending in or issued by any other country, any competent court having jurisdiction over the subject of the Patent Controversy sitting in the capital of such country (or if there is not any such competent court in the capital, a location reasonably proximate to the capital), and each Party irrevocably submits to the jurisdiction of such court. Each Party agrees not to raise any objection at any time to the laying or maintaining of the venue of any action, suit or proceeding for such purpose in any such court, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum, including any *forum non conveniens* argument, and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such court does not have any jurisdiction over such Party.

12.4 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may assign this Agreement without such consent to its Affiliate or its successor in interest by way of merger, acquisition, or sale of all or substantially all of its assets. Any Party making any a permitted assignment shall give the other Party a prompt written notice of such assignment. Any permitted assignment shall be binding on the successors, heirs, and assigns of the assigning Party. Any assignment in violation of this Section 12.4 shall be null and void.

12.5 Publicity — Use of Name. Neither Party shall be permitted to use the name, or any proprietary trademarks, tradenames, trade dress or logos ("***Marks***") of the other Party, or its Affiliates, or its Sublicensees, in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party.

12.6 Severability. If any provision of this Agreement is held to be invalid or unenforceable by an arbitrator or any court of competent jurisdiction from which no appeal can be or is taken, the provision shall to that extent be considered severed from this Agreement, and the remainder of this Agreement will remain in full force and effect. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the Parties' original goals and interests when entering this Agreement may be realized and protected.

12.7 Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder, or to insist upon compliance with any term or condition of this Agreement, shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. Any waiver by a Party of a particular breach or default by the other Party shall not operate or be construed as a waiver of any subsequent breach or default by the other Party.

12.8 Agency. Neither Party is, nor will be deemed to be an employee, agent, or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to speak for, represent, or obligate the other Party in any way without prior written authority from the other Party.

12.9 Exhibits. All Exhibits to this Agreement shall form an integral part of this Agreement.

12.10 Entire Understanding. This Agreement contains the entire understanding between the Parties hereto with respect to its subject matter and supersedes any and all prior agreements, understandings and arrangements, whether written or oral.

12.11 Amendments. No amendments of the terms and conditions of this Agreement shall be binding upon either Party hereto unless in writing and signed by both Parties.

12.12 Interpretation. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall he applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" or "includes" as used herein means including or includes, without limiting the generality of any description preceding such term. All references in this Agreement to the singular shall include the plural where applicable.

12.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which is an original, and all of which together constitute only one agreement between the Parties. The signatures of all the Parties do not need to be on the same counterpart for it to be effective. Delivery of an executed counterpart's signature page of this Agreement, by electronic mail in portable document format (.pdf) or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, has the same effect as delivery of an executed original of this Agreement.

12.14 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other Party shall be in writing, delivered by any lawful means to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to Hengrui: **Jiangsu Hengrui Medicine Co., Ltd.**
7 Kunlunshan Road,
Economy and Technology Development Zone.
Lianyungang, Jiangsu,
China

[***]

with a copy to (which will not constitute notice):

Greenberg Traurig, LLP
One International Place, Suite 2000
Boston, MA 02110
Attention: Fang Xie, Ph.D.

If to Arcutis: **Arcutis, Inc.**
70 Willow Road, Suite 200
Menlo Park, CA 94025 USA
Attention: President

with a copy to (which will not constitute notice):

Fenwick and West, LLP
555 California St.
12th Floor
San Francisco, CA 94104
Attention: Matt Rossiter; Stefano Quintini

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement effective as of the Effective Date.

Jiangsu Hengrui Medicine Co., Ltd.

By: /s/ Piaojang Sun
Name: Piaojang Sun
Title: Chairman of the Board

Arcutis, Inc.

By: /s/ Bhaskar Chaudhuri
Name: Bhaskar Chaudhuri
Title: Executive Chairman

Exhibit A
Licensed Patent Rights

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
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[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Exhibit B
Option Period Studies

[***]

AMENDMENT NO. 1 TO
EXCLUSIVE OPTION AND LICENSE AGREEMENT

THIS AMENDMENT NO. 1 (this "***Amendment***") to the Exclusive Option and License Agreement dated as of January 4, 2018 (the "***Agreement***"), by and between Arcutis, Inc., a United States corporation incorporated in the State of Delaware ("***Arcutis***") and Jiangsu Hengrui Medicine Co., Ltd., a Chinese corporation ("***Hengrui***") is entered into as of _____, 2019 (the "***Amendment Effective Date***").

RECITALS

A. Pursuant to the Agreement, Hengrui granted Arcutis an exclusive option to obtain an exclusive license under the Licensed Technology for the development of topical therapeutic products.

B. The parties now desire to amend the Agreement to extend the Option Period.

NOW, THEREFORE, in consideration of the mutual promises contained herein, the parties agree as follows:

1. Definitions. Except as defined in this Amendment, the capitalized terms used herein shall have the same meanings as ascribed to them in the Agreement.

2. Amendment. Section 1.24 (Option Period) is hereby deleted and replaced with the following:

"***Option Period***" means the period of time commencing on the Effective Date and ending on January 1, 2020.

3. Effect of Amendment. The parties agree that this Amendment shall be deemed to have been in full force and effective as of the Amendment Effective Date. All the terms and conditions of the Agreement shall continue in full force and effect except as modified by the terms of this Amendment.

4. Counterparts. This Amendment may be executed in counterparts, each of which shall be deemed an original and all of which taken together constitute one instrument.

IN WITNESS WHEREOF, Arcutis and Hengrui have caused this Amendment to be executed and delivered by their respective officers thereunto duly authorized, all as of the Amendment Effective Date.

Arcutis, Inc.	**Jiangsu Hengrui Medicine Co., Ltd.**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED, AND HAS BEEN MARKED WITH "[***]" TO INDICATE WHERE OMISSIONS HAVE BEEN MADE.

FORMULATION COLLABORATION AGREEMENT

THIS FORMULATION COLLABORATION AGREEMENT (this "**Agreement**") is made as of June 28, 2019 (the "**Effective Date**"), by and between **HAWKEYE THERAPEUTICS, INC**., a Delaware corporation, with its principal place of business located at 70 Willow Road, Menlo Park, CA 94025 ("**Hawkeye**"), and Arcutis, Inc., a Delaware corporation, having its principal place of business at 2945 Townsgate Road, Suite 110, Westlake Village, CA 91361 ("**Arcutis**"). Hawkeye and Arcutis are sometimes referred to herein individually as a "Party" and collectively as the "**Parties**."

RECITALS

WHEREAS, Hawkeye is a biotechnology company established with the intent to research and develop pharmaceutical products for [***] indications;

WHEREAS, Arcutis is a biopharmaceutical company focused on developing and commercializing pharmaceutical products for dermatological indications, including formulations of roflumilast for dermatological uses; and

WHEREAS, Hawkeye and Arcutis desire to collaborate on the research and development of one or more [***] formulations of roflumilast, all under the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and premises contained in this Agreement, the receipt and sufficiency of which are hereby expressly acknowledged, the Parties hereto agree as follows:

1. CERTAIN DEFINITIONS.

1.1 "**Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.2 "**Arcutis Know-How**" shall mean information, procedures, techniques, and other Know-How Controlled by Arcutis as of the Effective Date or at any time during the Term, in each case that are necessary for the development of, or incorporated into, the [***] Formulations.

1.3 "**Arcutis Personnel**" shall mean: (a) [***]; and (b) any other employees of Arcutis who are engaged to conduct activities under the Collaboration by the Parties' mutual written agreement.

1.4 "**Collaboration**" shall mean the activities set forth in the Collaboration Plan for the research and development of [***] Formulations.

1.5 "**Collaboration IP**" shall mean: (a) any and all Know-How (for clarity including formulations and products) arising from, or developed during, the Collaboration by or on behalf of Arcutis, either solely or jointly with others or with Hawkeye; and (b) any and all intellectual property rights in and to the Know-How described in subsection (a), including any patent applications and patents claiming or describing such Know-How.

1.6 "**Collaboration Plan**" has the meaning set forth in Section 2.1.

1.7 "**Common Stock**" means the common stock, par value $0.0001, of Hawkeye.

1.8 "**Control**" means, with respect to any information or other intellectual property right, or physical materials, ownership or possession by a Party, or, where expressly provided, its affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such information or other intellectual property right, or physical materials without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any third party, or without giving rise to any financial or other obligation to any third party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license or sublicense.

1.9 "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.10 "**IPO**" means Hawkeye's first underwritten public offering of its Common Stock under the Act.

1.11 "**Know-How**" means all technical information, know-how, results, data, inventions, discoveries, trade secrets, specifications, instructions, processes, protocols, formulae, compositions of matter, products, formulations, assays, and other physical, biological, or chemical materials, expertise, together with all documents, data, filings and instructions relating thereto. Know-How excludes patent applications and patents.

1.12 "[***] **Indications**" shall mean [***]

1.13 "[***] **Formulations**" shall mean products containing roflumilast that are formulated [***] which may include but are not limited to [***].

1.14 "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.15 "**Territory**" means worldwide.

2. COLLABORATION.

2.1 Collaboration Plan; Overview. As of the Effective Date, the Parties have agreed on a plan setting forth the scope and timeline of the Collaboration, attached to this Agreement as Exhibit A (the "**Collaboration Plan**"). The Collaboration Plan may be modified only by the Parties' mutual written consent, provided that neither Party shall unreasonably withhold its

consent to any modification that is reasonably supported by scientific, commercial or intellectual property considerations. Subject to the terms and conditions of this Agreement, during the Term the Parties shall carry out the activities set forth in the Collaboration Plan and collaborate to accomplish the objective of developing one or more [***] Formulations.

2.2 Arcutis Personnel. Arcutis shall carry out the Collaboration through Arcutis Personnel, and shall ensure that such Arcutis Personnel understand and agree to abide by the terms and conditions of this Agreement and to segregate the activities under the Collaboration from other activities carried out by such Arcutis Personnel on behalf of Arcutis. Arcutis shall not engage any employee, consultant or other subcontractor other than the Arcutis Personnel in the Collaboration without the prior written consent of Hawkeye, which consent shall not be unreasonably withheld, conditioned or delayed. [***]

2.3 Compliance with the Law. Each Party shall carry out the Collaboration in a competent and professional manner, in accordance with the terms and conditions contained in this Agreement, and in compliance with all applicable laws, rules and regulations.

2.4 [***]

(a) [***]

(b) [***]

[***]

3. EQUITY AND PAYMENT.

3.1 Common Stock Purchase. As consideration for, and commensurate with, the execution and delivery of this Agreement, Hawkeye will grant Arcutis the right to purchase 995,000 fully-vested shares of Common Stock (equal to 19.9% of the issued and outstanding shares of the Common Stock of Hawkeye, inclusive of the Common Stock issued and sold to Arcutis pursuant to this Section 3.1) at the fair market value as determined by the board of directors of Hawkeye on the date of grant (the "**Grant**"). The Grant will be governed by the terms and conditions of Hawkeye's standard form of common stock purchase agreement as agreed between the parties.

3.2 Additional Common Stock. Except in the event that this Agreement is terminated pursuant to Section 7.2 due to a material breach by Arcutis, if and when Hawkeye (a) issues and sells to investors in a bona fide equity financing (the "**Series A Financing**") shares of its preferred stock (the "**Series A Preferred Stock**"), and (b) receives total proceeds of at least $5,000,000 (excluding the conversion of convertible promissory notes or other convertible securities issued for capital raising purposes (e.g., Simple Agreements for Future Equity)), Hawkeye shall issue to Arcutis a number of fully-paid and fully-vested shares of Common Stock (pursuant to the same form of common stock purchase agreement contemplated in Section 3.1 as applicable) determined by dividing (i) $2,000,000, by (ii) an amount equal to the cash price paid per share for Series A Preferred Stock by the investors in the Series A Financing, rounded down to the nearest whole share.

3.3 Further Assurances. Arcutis will deliver to Hawkeye any documentation reasonably required by Hawkeye, and consistent with documentation requested of other Hawkeye stockholders, including any purchase agreement, any investor rights agreement, any stockholder or voting agreement, right of first refusal and co-sale agreement and other ancillary agreements, with customary representations and warranties and transfer restrictions (including, without limitation, a lock-up agreement in connection with an initial public offering). Hawkeye shall not be required to issue or deliver the capital stock subject to Section 3.2 until Arcutis has delivered to Hawkeye any such documentation.

3.4 Reimbursement for Services. Hawkeye shall reimburse Arcutis for all expenses incurred by Arcutis during the Term in carrying out activities in accordance with the Collaboration Plan, including support for the Arcutis Personnel at $[***], and reimbursement for costs of materials and equipment, pass-through expenses, and travel expenses to the extent requested and approved in advance by Hawkeye.

3.5 Invoices; Payment. Unless otherwise agreed by the Parties in writing, Arcutis shall provide to Hawkeye invoices on a monthly basis within ten (10) days after the end of each calendar month, each such invoice summarizing the services performed during that period of time for research and development of [***] Formulations under this Agreement and an accounting of costs and expenses incurred and accrued to date for the reimbursable expenses therefor. Hawkeye shall pay the full undisputed portion of each invoice within thirty (30) days of receipt thereof, and shall concurrently provide Arcutis with a written statement and supporting documentation regarding the unpaid amounts disputed in good faith. Hawkeye shall not be obligated to pay any amounts that exceed the budget set forth in the Collaboration Plan, unless such excess amounts have been approved in writing by Hawkeye in advance.

3.6 Records Audit. Hawkeye, through an independent accounting firm appointed by Hawkeye and reasonably acceptable to Arcutis, subject to written confidentiality obligations at least as protective as those contained herein (such accounting firm, the "**Auditor**"), at Hawkeye's sole expense, shall have the right to audit Arcutis's financial records relating to payments received under this Agreement for the sole purpose of verifying the accuracy of such payments during the Term and for three (3) years thereafter; *provided*, that any such audit(s) shall be conducted upon reasonable advance written notice, in any event no less than thirty (30) days prior written notice, to Arcutis and during Arcutis's normal business hours, in a manner that does not interfere with Arcutis's business activities. Hawkeye agrees to, and to cause the Auditor to, hold in confidence all information received and all information learned in the course of any audit or inspection, except to the extent that such information is not confidential and/or it is necessary to disclose it to enforce its rights under this Agreement or if disclosure is required by applicable law. For the avoidance of doubt, the information provided by Arcutis pursuant to this Section 3.6 shall be deemed to be Confidential Information of Arcutis hereunder.

4. OWNERSHIP OF COLLABORATION IP.

4.1 Collaboration IP. [***]

4.2 Assignment; Further Action. [***]

4.3 Patent Prosecution. [***]

4.4 Records of Collaboration IP. [***]

4.5 License Grants.

(a) Subject to the terms and conditions of this Agreement, Arcutis hereby grants to Hawkeye a perpetual, irrevocable, fully-paid, royalty-free, non-exclusive license, with the right to grant sublicenses, under the Arcutis Know-How to research, develop, manufacture, have manufactured, use, sell, offer for sale, import, export or otherwise commercialize products [***]

(b) Subject to the terms and conditions of this Agreement, Hawkeye hereby grants to Arcutis a perpetual, irrevocable, fully-paid, royalty-free, exclusive (other than the right to research, manufacture and have manufactured, which shall be non-exclusive) license, with the right to grant sublicenses [***] Hawkeye shall retain the sole and exclusive right (as to Arcutis) to practice and exploit the Collaboration IP for any and all other purposes, including to research, develop, manufacture, have manufactured, use, sell, offer for sale, import, export or otherwise commercialize [***]

4.6 Other Intellectual Property. The licenses granted under Section 4.5 do not include the right for Hawkeye to practice any patent applications, patents or other Know-How other than the Arcutis Know-How, whether owned or in-licensed by Arcutis or a third party (collectively, the "**Excluded IP**") unless and until the Parties otherwise agree in a separate license agreement. Prior to the use of any Excluded IP in the Collaboration or incorporating any Excluded IP in an [***] Formulation, Arcutis shall notify Hawkeye and identify such Excluded IP and obtain Hawkeye's written consent to do so.

4.7 No Implied License. Neither Hawkeye nor Arcutis transfers to the other by operation of this Agreement any patent right, copyright right, trademark right or other proprietary right of any Party, except as expressly set forth in this Agreement.

5. CONFIDENTIALITY.

5.1 Confidentiality Obligation. During the term of this Agreement and for a period of five (5) years thereafter, each Party (the "**Receiving Party**") will maintain all Confidential Information (as defined below) of the other Party (the "**Disclosing Party**") as confidential and will not disclose any such Confidential Information or use any such Confidential Information for any purpose, except (a) as expressly authorized by this Agreement, (b) as permitted by Section 5.3, for the purpose of exercising its rights or fulfilling its obligations under this Agreement, or (d) to its employees, agents, consultants, subcontractors approved by the Disclosing Party and other representatives who require access to such information to accomplish the purposes of this Agreement, so long as such persons are under obligations regarding the confidentiality of such Confidential Information and the ownership of Collaboration IP that are consistent with, and no less protective to the Disclosing Party than, the terms of this Agreement. The Receiving Party may use the Disclosing Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party will use at least the same standard of care as it uses to protect its own confidential information to ensure that its

employees, agents, consultants, subcontractors approved by the Disclosing Party and other representatives do not disclose or make any unauthorized use of the Disclosing' Party's Confidential Information. The Receiving Party will promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information.

5.2 Definition. For the purpose of this Agreement, with respect to each Party, "**Confidential Information**" means all information provided by or on behalf of the Disclosing Party to the Receiving Party in connection with this Agreement, whether in oral, written, graphic or electronic form. Notwithstanding the foregoing, a Disclosing Party's Confidential Information will not include any information which a Receiving Party can demonstrate by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its employees, agents, consultants or subcontractors, generally known or available; (b) is known by the Receiving Party at the time of receiving such information or is independently developed by the Receiving Party without access to or use of the Disclosing Party's Confidential Information, as evidenced by the Receiving Party's pre-existing written records; or (c) is hereafter furnished to the Receiving Party by a third party, as a matter of right and without restriction on disclosure. Collaboration IP shall constitute Hawkeye's Confidential Information under this Agreement.

5.3 Authorized Disclosure. Notwithstanding Section 5.1, the Receiving Party may disclose the Disclosing Party's Confidential Information, without violating its obligations under this Agreement, to the extent the disclosure is required by applicable law or by a valid order of a court or other governmental body having jurisdiction, provided that the Receiving Party gives reasonable prior written notice to the Disclosing Party of such required disclosure and, at the Disclosing Party's request and expense, cooperates with the Disclosing Party's efforts to obtain a protective order preventing or limiting the disclosure, requiring that the Disclosing Party's Confidential Information so disclosed be used only for the purposes for which the law or order requires, and/or to obtain other confidential treatment of such Confidential Information.

5.4 Third Party Confidential Information. Neither Party shall disclose to the other Party any confidential or proprietary information that belongs to any third party.

6. REPRESENTATIONS AND WARRANTIES.

6.1 Mutual Representations and Warranties. Each Party represents and warrants that (a) it has full power and authority to enter into this Agreement, (b) this Agreement has been duly authorized, and (c) this Agreement is binding upon it.

6.2 Arcutis Representations and Warranties. Arcutis represents and warrants that: (a) the terms of this Agreement are not inconsistent with its other contractual arrangements; and (b) Arcutis is not constrained by any existing agreement in fulfilling its obligations under this Agreement, including the assignment of rights and grant of the licenses under Article 4.

6.3 Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

6.4 Limitation of Liability. EXCEPT FOR BREACH OF ARTICLE 5, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY LOST PROFITS, LOST SAVINGS, OR ANY OTHER INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, OTHER THAN DAMAGES ARISING OUT OF FRAUD OR WILLFUL MISCONDUCT; *provided*, *however*, that this Section 6.4 shall not be construed to limit either Party's indemnification obligations under Article 8.

7. TERM AND TERMINATION.

7.1 Term. The term of this Agreement (the "**Term**") shall commence on the Effective Date and shall continue for a period of six (6) months after the Effective Date, unless extended by a written mutual agreement of the Parties.

7.2 Termination of Agreement for Material Breach. A Party may terminate this Agreement for material breach of this Agreement by the other Party upon thirty (30) days' written notice specifying the nature of the breach, if such breach has not been cured within such thirty (30)-day period.

7.3 Effects of Expiration or Termination.

(a) Costs Incurred. In the event of expiration or termination of this Agreement, Hawkeye shall pay to Arcutis all sums owing to Arcutis for Collaboration completed up to the expiration date or effective termination date and all non-cancelable obligations reasonably incurred before such date. Subject to the preceding sentence, Arcutis shall refund to Hawkeye any prepaid amounts not earned by Arcutis prior to the expiration date or effective date of such termination.

(b) Final Report of Collaboration IP. Arcutis shall provide Hawkeye with a final report on the Collaboration IP within thirty (30) days after the expiration date or the effective date of termination, as the case may be.

(c) Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Articles 1, 5, 8 and 9 and Sections 2.4, 2.5, 3.2 (other than termination of this Agreement under Section 7.2 for Arcutis' material breach), 3.6, 4.1, 4.2, 4.3, 4.4, 4.5, 6.3, 6.4, 7.2 and this 7.3(c) shall survive expiration or termination of this Agreement.

8. INDEMNIFICATION.

8.1 Hawkeye Indemnification. Hawkeye hereby agrees to save, defend, indemnify and hold harmless Arcutis and its officers, directors, employees, consultants and agents ("**Arcutis Indemnitees**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**"), to which any such

Arcutis Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any third party to the extent such Losses arise out of the material breach by Hawkeye of any representation, warranty, covenant or agreement made by it under this Agreement, the practice or exploitation of the Arcutis Know-How under the license granted to it under this Agreement, or the gross negligence or willful misconduct of any Hawkeye Indemnitee; except, in each case, to the extent such Losses result from the material breach by Arcutis of any representation, warranty, covenant or agreement made by it under this Agreement or the negligence or willful misconduct of any Arcutis Indemnitee.

8.2 Arcutis Indemnification. Arcutis hereby agrees to save, defend, indemnify and hold harmless Hawkeye and its officers, directors, employees, consultants, contractors and agents ("Hawkeye Indemnitees") from and against any and all Losses to which any such Hawkeye Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any third party to the extent such Losses arise out of the material breach by Arcutis of any representation, warranty, covenant or agreement made by it under this Agreement, the practice or exploitation of the Collaboration IP under the license granted to it under this Agreement or the gross negligence or willful misconduct of any Arcutis Indemnitee; except, in each case, to the extent such Losses result from the material breach by Hawkeye of any representation, warranty, covenant or agreement made by it under this Agreement or the gross negligence or willful misconduct of any Hawkeye Indemnitee.

8.3 General Conditions of Indemnification. A Party's agreement to indemnify, defend and hold the other Party (the "**Indemnified Party**") and its related entities harmless is conditioned upon the Indemnified Party: (a) providing written notice to the first Party (the "**Indemnifying Party**") of any claim, demand or action arising out of the indemnified activities within thirty (30) days after the Indemnified Party has knowledge of such claim, demand or action; (b) permitting the Indemnifying Party to assume full responsibility and authority to investigate, prepare for and defend against any such claim or demand; (c) assisting the Indemnifying Party, at the Indemnifying Party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand; and (d) not compromising or settling such claim or demand without the Indemnifying Party's written consent.

9. MISCELLANEOUS.

9.1 Independent Contractor Relationship. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Arcutis and Hawkeye, or to constitute one as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

9.2 Minimum Financing Amount. Commensurate with this Agreement, Hawkeye shall issue and sell one or more convertible promissory notes having an aggregate principal amount of at least $500,000.

9.3 Legal Review. Notwithstanding anything contained in this Agreement to the contrary, each of the Parties will be responsible for their own legal fees and associated costs and expenses associated with the matters contemplated in these terms.

9.4 Use of Names. Neither Party shall use the other Party's name or the names of the other Party's employees in any advertising or sales promotional material or in any publication without prior written permission of the other Party.

9.5 Force Majeure. In the event of a delay caused by inclement weather, fire, flood, act of war, act of terrorism, act of God, act of governmental officials or agencies, or any like cause beyond the control of the Parties, the Party or Parties so affected shall be excused from performance hereunder for the period of time attributable to such delay, which may extend beyond the time lost due to one or more of the causes mentioned above. In the event of any such delay, the Parties may, in their sole discretion, revise this Agreement by changing the schedule of payments, the performance period, and other provisions, as appropriate, by mutual written agreement.

9.6 Applicable Law; Jurisdiction and Venue. This Agreement shall be governed by and construed in accordance with the laws of California, without regard to its conflicts of laws principles. Each Party: (a) irrevocably and unconditionally consents and submits to the jurisdiction of the state and federal courts located in San Francisco, California for purposes of any action, suit or proceeding arising out of or relating to this Agreement; (b) agrees that service of any process, summons, notice or document by U.S. registered mail to the address given on the signature page of this Agreement shall be effective service of process for any such action, suit or proceeding brought against such Party; (c) irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this Agreement in any state or federal court located in San Francisco, California; and (d) irrevocably and unconditionally waives the right to plead or claim, and irrevocably and unconditionally agrees not to plead or claim, that any action, suit or proceeding arising out of or relating to this Agreement that is brought in any state or federal court located in San Francisco, California been brought in an inconvenient forum.

9.7 Injunctive Relief. Each Party hereby acknowledges and agrees that in the event of such Party's breach of any provision of this Agreement relating to Confidential Information and/or intellectual property (including, without limitation, Article 4 and Article 5), the other Party would suffer an irreparable injury such that no remedy at law would adequately protect or appropriately compensate such other Party for such injury. Accordingly, each Party agrees that the other Party shall have the right to enforce this Agreement and any of such provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the other Party may have for a breach of this Agreement.

9.8 Entire Agreement; Amendment. This Agreement constitutes the final, complete and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes all prior understandings and agreements relating to its subject matter. This Agreement may not be changed, modified, amended or supplemented except by a written instrument signed by an authorized representative of each of Hawkeye and Arcutis.

9.9 Successors and Assigns. Neither Party may assign this Agreement without the prior written consent of the other Party; *provided*, *however*, that each Party may assign this Agreement without the other Party's consent to its affiliates or in connection with the transfer or sale of all or substantially all of its stock, assets or business to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. Any attempted assignment of this Agreement not in compliance with this Section 9.9 shall be null and void. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement. This Agreement shall inure to the benefit of and be binding upon each Party signatory hereto, its successors and permitted assigns, subsidiaries and affiliates.

9.10 Severability. If any provision of this Agreement is found by a court of competent jurisdiction to be unenforceable, then such provision will be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it will be severed from the remainder of this Agreement. The remainder of this Agreement will remain in full force and effect, unless the severed provision is essential and material to the rights or benefits received by either Party. In such event, the Parties will negotiate, in good faith, and substitute a valid and enforceable provision or agreement that most nearly implements the Parties' intent in entering into this Agreement.

9.11 Non-Waiver. No failure or delay of one of the Parties to insist upon strict performance of any of its rights or powers under this Agreement shall operate as a waiver thereof, nor shall any other single or partial exercise of such right or power preclude any other further exercise of any rights or remedies provided by law.

9.12 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, three (3) days after the date of postmark; or (c) if delivered by express courier, the next business day the courier regularly makes deliveries to the addressee's location.

If to Hawkeye:	c/o Frazier Healthcare Partners 70 Willow Rd. Menlo Park, CA 94025 Attention: Dan Estes
If to Arcutis:	Arcutis, Inc. 2945 Townsgate Road, Suite 110 Westlake Village, CA, 91361 Attention: President

9.13 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include

the plural where applicable. Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such Section and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement, shall be in the English language.

9.14 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

[signature page follows]

IN WITNESS WHEREOF, the parties have by duly authorized persons executed this Formulation Collaboration Agreement as of the Effective Date.

HAWKEYE THERAPEUTICS, INC.

By: /s/Daniel J. Estes
Name: Daniel J. Estes
Title: Chief Executive Officer
Date: June 28, 2019

ARCUTIS, INC.

By: /s/ Frank Watanabe
Name: Frank Watanabe
Title: President
Date: June 28, 2019

EXHIBIT A – COLLABORATION PLAN

1. [***]