UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2021

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For transition period from to

Commission File Number: 001-39186

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-2974255**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
3027 Townsgate Road Suite 300 **Westlake Village, California** **(Address of Principal Executive Offices)**	**91361** **(Zip Code)**

(805) 418-5006

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001	**ARQT**	**The Nasdaq Global Select Market**

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an 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 pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

The number of shares of the registrant’s Common Stock outstanding as of October 29, 2021 was 50,295,278.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q may be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “forecasts,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to statements regarding our future results of operations and financial position, industry and business trends, stock compensation, business strategy, plans, market growth, and our objectives for future operations.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. Forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed in Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. The forward-looking statements in this Quarterly Report on Form 10-Q are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance, and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained in this Quarterly Report on Form 10-Q, whether as a result of any new information, future events, or otherwise.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part II Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our Class A common stock. The principal risks and uncertainties affecting our business include the following:

- We are a late-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 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 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 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;
- 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;
- 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;
- 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;
- 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 a company, we have never 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;
- 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;
- 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;
- We currently have limited sales, marketing, or distribution capabilities and have no experience as a company in commercializing products;
- We will need to increase the size of our organization, and we may experience difficulties in executing our growth strategy and managing any growth;
- 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;
- 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 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 roflumilast cream, roflumilast foam, ARQ-252, ARQ-255, or any future product candidates;
- Risks related to our intellectual property could materially adversely impact our business, competitive position, financial condition, and results of operations;
- Risks related to government regulation of our industry and required approvals could materially adversely impact our business, competitive position, financial condition, and results of operations; and
- Future litigation could have a material adverse effect on our business and results of operations.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Balance Sheets
(In thousands, except share and par value)

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,778	$ 65,082
Restricted cash	1,542	1,542
Marketable securities	315,492	219,359
Prepaid expenses and other current assets	12,958	6,843
Total current assets	381,770	292,826
Property, plant, and equipment, net	2,045	2,016
Operating lease right-of-use asset	3,115	3,349
Other assets	78	78
Total assets	$ 387,008	$ 298,269
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,871	$ 7,140
Accrued liabilities	13,881	15,462
Operating lease liability	306	—
Total current liabilities	19,058	22,602
Operating lease liability, noncurrent	4,924	4,964
Other long-term liabilities	31	82
Total liabilities	24,013	27,648
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020;	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at September 30, 2021 and December 31, 2020; 50,266,730 and 43,677,817 shares issued at September 30, 2021 and December 31, 2020, respectively; 50,134,813 and 43,338,438 shares outstanding at September 30, 2021 and December 31, 2020, respectively	5	4
Additional paid-in capital	699,988	472,569
Accumulated other comprehensive loss	(18)	(2)
Accumulated deficit	(336,980)	(201,950)
Total stockholders' equity	362,995	270,621
Total liabilities and stockholders' equity	$ 387,008	$ 298,269

The accompanying notes are an integral part of these unaudited condensed financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 40,604	$ 32,743	$ 93,000	$ 87,934
General and administrative	16,474	5,560	42,243	14,647
Total operating expenses	57,078	38,303	135,243	102,581
Loss from operations	(57,078)	(38,303)	(135,243)	(102,581)
Other income, net	98	99	213	952
Net loss	$ (56,980)	$ (38,204)	$ (135,030)	$ (101,629)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	18	4	(16)	5
Comprehensive loss	$ (56,962)	$ (38,200)	$ (135,046)	$ (101,624)
Per share information:				
Net loss per share, basic and diluted	$ (1.14)	$ (1.01)	$ (2.75)	$ (3.06)
Weighted-average shares used in computing net loss per share, basic and diluted	50,097,851	37,748,454	49,136,768	33,214,005

The accompanying notes are an integral part of these unaudited condensed financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)
(unaudited)

	Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance—December 31, 2019	24,385,388	$ 166,491	2,120,853	$ —	$ 1,244	$ (1)	$ (66,272)	$ (65,029)
Conversion of preferred stock into common stock upon initial public offering	(24,385,388)	(166,491)	24,385,388	2	166,489	—	—	166,491
Issuance of shares of common stock for initial public offering, net of issuance costs of $16,040	—	—	10,781,250	1	167,240	—	—	167,241
Issuance of shares of common stock upon the exercise of stock options	—	—	51,147	—	152	—	—	152
Vesting of founder shares subject to repurchase	—	—	68,931	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	64,428	—	30	—	—	30
Stock-based compensation expense	—	—	—	—	990	—	—	990
Unrealized gain on marketable securities	—	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	—	(28,013)	(28,013)
Balance—March 31, 2020	—	$ —	37,471,997	$ 3	$ 336,145	$ 19	$ (94,285)	$ 241,882
Issuance of common stock upon the exercise of stock options	—	—	14,875	—	25	—	—	25
Vesting of founder shares subject to repurchase	—	—	68,932	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	114,392	—	111	—	—	111
Shares issued pursuant to the employee stock purchase plan			19,862	—	287	—	—	287
Stock-based compensation expense	—	—	—	—	2,049	—	—	2,049
Unrealized loss on marketable securities	—	—	—	—	—	(19)	—	(19)
Net loss	—	—	—	—	—	—	(35,412)	(35,412)
Balance—June 30, 2020	—	$ —	37,690,058	$ 3	$ 338,617	$ —	$ (129,697)	$ 208,923
Issuance of common stock upon the exercise of stock options	—	—	28,908	—	34	—	—	34
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	79,923	1	52	—	—	53
Stock-based compensation expense	—	—	—	—	2,261	—	—	2,261
Unrealized gain on marketable securities	—	—	—	—	—	4	—	4
Net loss	—	—	—	—	—	—	(38,204)	(38,204)
Balance—September 30, 2020	—	$ —	37,798,889	$ 4	$ 340,964	$ 4	$ (167,901)	$ 173,071

The accompanying notes are an integral part of these unaudited condensed financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2020	—	$ —	43,338,438	$ 4	$ 472,569	$ (2)	$ (201,950)	$ 270,621
Issuance of shares of common stock for public offering, net of issuance costs of $603	—	—	6,325,000	1	207,489	—	—	207,490
Issuance of common stock upon the exercise of stock options	—	—	111,282	—	325	—	—	325
Issuance of common stock upon the vesting of restricted stock units	—	—	32,362	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	79,925	—	53	—	—	53
Stock-based compensation expense	—	—	—	—	8,503	—	—	8,503
Unrealized gain on marketable securities	—	—	—	—	—	44	—	44
Net loss	—	—	—	—	—	—	(36,042)	(36,042)
Balance—March 31, 2021	—	$ —	49,887,007	$ 5	$ 688,939	$ 42	$ (237,992)	$ 450,994
Issuance of common stock upon the exercise of stock options	—	—	62,314	—	710	—	—	710
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	73,623	—	52	—	—	52
Shares issued pursuant to the employee stock purchase plan	—	—	22,658	—	478	—	—	478
Stock-based compensation expense	—	—	—	—	4,340	—	—	4,340
Unrealized loss on marketable securities	—	—	—	—	—	(78)	—	(78)
Net loss	—	—	—	—	—	—	(42,008)	(42,008)
Balance—June 30, 2021	—	$ —	50,045,602	$ 5	$ 694,519	$ (36)	$ (280,000)	$ 414,488
Issuance of common stock upon the exercise of stock options	—	—	30,297	—	63	—	—	63
Issuance of common stock upon the vesting of restricted stock units	—	—	5,000	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	53,914	—	43	—	—	43
Stock-based compensation expense	—	—	—	—	5,363	—	—	5,363
Unrealized gain on marketable securities	—	—	—	—	—	18	—	18
Net Loss	—	—	—	—	—	—	(56,980)	(56,980)
Balance—September 30, 2021	—	$ —	50,134,813	$ 5	$ 699,988	$ (18)	$ (336,980)	$ 362,995

The accompanying notes are an integral part of these unaudited condensed financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Statements of Cash Flows
(In thousands)
(unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (135,030)	$ (101,629)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	318	87
Non-cash lease expense	234	202
Net amortization/accretion on marketable securities	2,569	(307)
Stock-based compensation expense	18,206	5,300
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(6,115)	(369)
Accounts payable	(2,146)	3,682
Accrued liabilities	(1,220)	12,602
Operating lease liabilities	266	(30)
Net cash used in operating activities	(122,918)	(80,462)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(244,268)	(179,364)
Proceeds from maturities of marketable securities	145,550	73,600
Purchases of property and equipment	(734)	(168)
Net cash used in investing activities	(99,452)	(105,932)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	1,098	307
Proceeds from initial public offering, net of issuance costs	—	168,642
Proceeds from issuance of common stock, net of issuance costs	207,490	—
Proceeds from issuance of common stock pursuant to employee stock purchase plan	478	287
Payment of financing costs	—	(471)
Net cash provided by financing activities	209,066	168,765
Net decrease in cash, cash equivalents, and restricted cash	(13,304)	(17,629)
Cash, cash equivalents, and restricted cash at beginning of period	66,624	63,336
Cash, cash equivalents, and restricted cash at end of period	$ 53,320	$ 45,707
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Right-of-use asset obtained in exchange for lease liability	$ —	$ 3,645
Reduction in right-of-use asset upon reassessment of lease term	$ —	$ 139

The accompanying notes are an integral part of these unaudited condensed financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Financial Statements

(unaudited)

1. Organization and Description of Business

Arcutis Biotherapeutics, Inc., or the Company, is a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions. The Company's current portfolio is comprised of highly differentiated topical treatments with significant promise to treat immune-mediated dermatological diseases and conditions. The Company believes it has built the industry's leading platform for dermatologic product development. The Company's strategy is to focus on validated biological targets and to use our platform and deep dermatology expertise to develop differentiated products that have the potential to address the 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 while maximizing its probability of technical success.

On January 17, 2020, the Company's board of directors approved a 1-for-2.0007 reverse stock split of the Company's capital stock and the Company filed a certificate of amendment to its restated certificate of incorporation to effect the split. The par value and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the reverse split. All share and per share information included in the accompanying financial statements has been adjusted to reflect this reverse stock split.

Initial Public Offering and Follow-On Financings

On February 4, 2020, the Company closed an initial public offering (IPO) issuing and selling 10,781,250 shares of common stock at a public offering price of $17.00 per share, including 1,406,250 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. The aggregate net proceeds received by the Company from the offering were approximately $167.2 million, after deducting underwriting discounts, commissions, and offering related transaction costs. Upon the closing of the IPO, all of the outstanding shares of convertible preferred stock automatically converted into shares of common stock. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

On October 6, 2020, the Company completed a public offering of 4,000,000 shares of common stock at an offering price of $25.00 per share, receiving aggregate net proceeds of approximately $93.4 million after deducting the underwriting discounts, commissions, and offering related transaction costs. In addition, the Company concurrently sold 1,400,000 shares of common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a price per share equal to the public offering price, receiving net proceeds of $35.0 million.

On February 5, 2021, the Company completed a public offering of 6,325,000 shares of stock at an offering price of $35.00 per share, including 825,000 shares sold pursuant to the underwriters full exercise of their option to purchase additional shares. The aggregate net proceeds received by the Company were approximately $207.5 million, after deducting underwriting discounts, commissions, and offering related transaction costs.

At-the-Market (ATM) Offerings

On May 6, 2021, the Company entered into a sales agreement (Sales Agreement) with Cowen and Company, LLC (Cowen), under which the Company may from time to time issue and sell shares of its common stock through ATM offerings for an aggregate offering price of up to $100 million. Cowen will act as the Company's sales agent for the ATM program and is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold under the Sales Agreement. The Company has not yet issued or sold any shares of common stock through the ATM.

ARCUTIS BIOTHERAPEUTICS, INC.
Notes to Condensed Financial Statements
(unaudited)

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $337.0 million and $202.0 million as of September 30, 2021 and December 31, 2020, respectively. The Company had cash, cash equivalents, restricted cash, and marketable securities of $368.8 million and $286.0 million as of September 30, 2021 and December 31, 2020, respectively. Prior to selling common stock in its IPO and follow-on financings, the Company had 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 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.

Coronavirus Outbreak

In March 2020, the World Health Organization declared a pandemic related to the global novel coronavirus disease 2019 (COVID-19) outbreak. As of November 4, 2021, the Company's operations have not been significantly impacted by the COVID-19 pandemic. The Company is monitoring the impact COVID-19 may have on the clinical development of its product candidates, including potential delays or modifications to its ongoing and planned trials. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned clinical trials.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed financial statements have been prepared in accordance with United States generally accepted accounting principles (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 condensed 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 (prior to the IPO completed in January 2020), 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.

Unaudited Interim Condensed Financial Statements

The interim condensed balance sheet as of September 30, 2021, the interim condensed statements of operations and comprehensive loss, and the condensed changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for the three and nine months ended September 30, 2021 and 2020 are unaudited. These unaudited interim condensed financial statements have been prepared on the same basis as the Company's audited 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 three- and nine-month periods are also unaudited. The condensed results of operations for the three

and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2020 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 unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2020.

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 U.S. Treasury securities.

Restricted Cash

As of September 30, 2021 and December 31, 2020, the Company held $1.5 million of restricted cash as collateral for a letter of credit related to our amended office space lease. See Note 7.

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, including those that have maturity dates beyond one year from the balance sheet date, are classified as current assets on the condensed balance sheets due to their highly liquid nature and availability for use in current operations.

Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive income (loss). Realized gains and losses as well as credit losses, if any, on marketable securities are included in other income, net. The Company evaluated the underlying credit quality and credit ratings of the issuers during the period. To date, no such credit losses have occurred or have been recorded. The cost of investments sold is based on the specific-identification method. Unrealized gains and losses on marketable securities are reported as a component of accumulated other comprehensive income (loss) on the condensed balance sheets. 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, cash equivalents, and marketable securities. 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 condensed 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.

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Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 3, 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 on the condensed 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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets which range from three to five years. Leasehold improvements are depreciated on a straight-line basis over the shorter of their estimated useful lives or lease terms. Maintenance and repairs are expensed as incurred. The Company reviews the carrying values of its property and equipment for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There were no impairments recognized during the three and nine months ended September 30, 2021 and 2020.

Leases

The Company determines if an arrangement is or contains a lease at inception. Right-of-use (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 lease payments over the lease term. The Company 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 is adjusted for 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 non-cancelable 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 agreements includes lease and non-lease components and the Company has elected to not separate such components for all classes of assets. 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.

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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 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 three and nine months ended September 30, 2021 and 2020, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Convertible Preferred Stock

Prior to its IPO, the Company classified its outstanding convertible preferred stock outside of stockholders' equity (deficit) on its condensed balance sheets as the requirements of triggering a deemed liquidation event, as defined within its amended and restated certificate of incorporation, were not entirely within the Company's control. In the event of such a deemed liquidation event, the proceeds from the event were to be distributed in accordance with the liquidation preferences, provided that the holders of convertible preferred stock had not converted their shares into common stock. The Company recorded the issuance of convertible preferred stock at the issuance price less related issuance costs. The Company did not adjust 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 have occurred. In connection with the IPO in February 2020, the Company's outstanding shares of convertible preferred stock were automatically converted into 24,385,388 shares of common 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 become 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.

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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 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 incurred in relation to the unrecognized tax benefits.

The United States Congress enacted the American Rescue Plan Act on March 10, 2021, Families First Coronavirus Response Act (FFCR Act) on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) on March 27, 2020. The American Rescue Plan Act is a follow-up to the CARES Act, which continue the emergency economic stimulus package and includes spending and tax breaks to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of COVID-19. The American Rescue Plan Act, FFCR Act, and CARES Act include numerous tax-related provisions, including modifications to the limitations on business interest expense and net operating losses (NOLs), certain refundable employee retention credits, as well as a payment delay of employer payroll taxes in 2020 after the date of enactment. On June 29, 2020, the California State Assembly Bill 85 (Trailer Bill) was enacted which suspends the use of California NOL deductions and certain tax credits, including research and development credits, for the 2020, 2021, and 2022 tax years. The Company does not expect the American Rescue Plan Act, FFCR Act, CARES Act, or Trailer Bill to have a material impact on the Company's financial statements.

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 (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. The Company currently does not consolidate any VIEs.

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.

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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 Adopted Accounting Pronouncements

There have been no new accounting pronouncements issued or effective that are expected to have a material impact on the Company's condensed 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):

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 51,778	$ —	$ —	$ 51,778
Commercial paper	—	111,384	—	111,384
Corporate debt securities	—	109,723	—	109,723
U.S. Treasury securities	94,385	—	—	94,385
Total assets	$ 146,163	$ 221,107	$ —	$ 367,270

(1) This balance includes cash requirements settled on a nightly basis.

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 65,082	$ —	$ —	$ 65,082
Commercial paper	—	45,518	—	45,518
U.S. Treasury securities	173,841	—	—	173,841
Total assets	$ 238,923	$ 45,518	$ —	$ 284,441

(1) This balance includes cash requirements settled on a nightly basis.

Commercial paper, corporate debt securities, money market funds, and U.S. Treasury 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.

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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):

	September 30, 2021			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 51,778	$ —	$ —	$ 51,778
Total cash and cash equivalents	$ 51,778	$ —	$ —	$ 51,778
Marketable securities:				
Commercial paper	$ 111,384	$ —	$ —	$ 111,384
Corporate debt securities	109,750	—	(27)	109,723
U.S. Treasury securities	94,376	9	—	94,385
Total marketable securities	$ 315,510	$ 9	$ (27)	$ 315,492

(1) This balance includes cash requirements settled on a nightly basis.

	December 31, 2020			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 65,082	$ —	$ —	$ 65,082
Total cash and cash equivalents	$ 65,082	$ —	$ —	$ 65,082
Marketable securities:				
Commercial paper	$ 45,518	$ —	$ —	$ 45,518
U.S. Treasury securities	173,843	7	(9)	173,841
Total marketable securities	$ 219,361	$ 7	$ (9)	$ 219,359

(1) This balance includes cash requirements settled on a nightly basis.

Realized gains or losses on investments for the three and nine months ended September 30, 2021 were not material. There were no realized gains or losses on investments for the three and nine months ended September 30, 2020. As of September 30, 2021 and December 31, 2020, unrealized losses on marketable securities were not material, and accordingly, no allowance for credit losses were recorded. As of September 30, 2021 and December 31, 2020, all securities have a maturity of 18 months or less and all securities with gross unrealized losses have been in a continuous loss position for less than one year.

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4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Prepaid clinical trial costs	$ 4,356	$ 4,865
Prepaid insurance	1,211	249
Tax credits	362	510
Other prepaid expenses and current assets	7,029	1,219
Total prepaid expenses and other current assets	$ 12,958	$ 6,843

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued compensation	$ 6,771	$ 4,434
Clinical trial accruals	4,076	9,754
Early exercise liability, current	79	176
Accrued expenses and other current liabilities	2,955	1,098
Total accrued liabilities	$ 13,881	$ 15,462

5. Property and Equipment, net

Property and equipment, net consists of the following (in thousands):

	Useful life (in years)	September 30, 2021	December 31, 2020
Computer hardware	3	$ 555	$ 286
Furniture and fixtures	5	248	230
Software	3	70	—
Construction in process		—	298
Leasehold improvements		1,568	1,280
Property and equipment, gross		2,441	2,094
Less accumulated depreciation		(396)	(78)
Property and equipment, net		$ 2,045	$ 2,016

Leasehold improvements are depreciated over the term of the lease. Depreciation expense was $116,000 and $318,000 for the three and nine months ended September 30, 2021, respectively, and $30,000 and $87,000 for the three and nine months ended September 30, 2020, respectively.

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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 (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 484,388 shares of Series B convertible preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. The Company subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product, which was recorded in research and development expense. The Company has agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specified regulatory approval milestones with respect to the AZ-Licensed Products, which includes $7.5 million upon U.S. Food and Drug Administration (FDA) approval of the Company's first product, 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.

There were no payments made or due in connection with AZ-Licensed Products for the three and nine months ended September 30, 2021 and 2020.

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. (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 Janus kinase type 1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, Canada, and the European Union (including for clarity the United Kingdom). The Company made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui Option and License Agreement, which was recorded as research and development expense. In December 2019, the Company exercised its exclusive option under the agreement, for which it made a $1.5 million cash payment, which was recorded in research and development expense, and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, 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.

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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.

There were no payments made or due in connection with Hengrui for the three and nine months ended September 30, 2021 and 2020.

Hawkeye Collaboration Agreement

In June 2019, the Company entered into a collaboration agreement, or Hawkeye Agreement, with Hawkeye Therapeutics, Inc. (Hawkeye), a related party with common ownership, for the 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.

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. 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. 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 VIE for which consolidation is not required as it is not the primary beneficiary.

7. Commitments and Contingencies

Operating Lease

The Company leases a facility in Westlake Village, California under an operating lease that commenced in February 2019. This lease was amended in April 2020 in order to relocate to a new expanded space comprising 22,643 square feet. At the time of the amendment, the Company reassessed the lease term of the original space in accordance with the option to terminate if leasing additional space in the same property. In connection with the reduction of the lease term for the original space, the Company reduced the ROU asset and lease liability balance by $123,000.

The Company recognized the ROU asset and lease liability for the new space on May 1, 2020, which was determined to be the lease commencement date, or the date on which the new space was made available to the Company for purposes of planning and constructing the leasehold improvements. The lease payment term for the new space began on December 30, 2020, which was 15 days after the leasehold improvements were substantially complete. The lease payments terminate 91 months thereafter, with a renewal option for a term of five years. The Company will have a one-time option to cancel the lease after month 67. The renewal and one-time cancellation options have not been considered in the determination of the ROU asset or lease liability as the Company did not consider it reasonably certain it would exercise these options.

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The lease is subject to fixed rate escalation increases with an initial base rent of $76,000 per month and includes rent free periods aggregating approximately one year. As a result, the Company recognizes rent expense on a straight-line basis for the full amount of the commitment including the minimum rent increases over the life of the lease and the free rent period. The amended lease agreement provided for a leasehold improvement allowance up to $1.25 million. It also required the Company to have an available letter of credit of $1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, in November 2020, the Company entered into a letter of credit for $1.5 million, which it secured with a restricted cash account in the same amount. The letter of credit and corresponding restricted cash will be reduced by $308,000 on the first, second, third, and fourth anniversary, and by $45,000 on the fifth anniversary from when the lease payment term began on December 30, 2020, with no further reductions thereafter.

In association with commencement of this new lease, the Company recorded lease liabilities and ROU assets of $3.6 million on its condensed balance sheet as of June 30, 2020. Since the Company was reasonably certain to incur costs equal to or exceeding the leasehold improvement allowance of $1.25 million, the allowance was treated as a lease incentive that was payable to the Company at the lease commencement date. Accordingly, the leasehold improvement allowance was included in the measurement of the consideration in the contract at commencement, and was recognized as a reduction in the ROU asset and lease liability. Upon completion of the leasehold improvements in December 2020, the $1.25 million allowance was reclassified from the lease liability to property and equipment on the condensed balance sheet as of December 31, 2020. The Company capitalized $320,000 of additional leasehold improvements, in excess of the $1.25 million allowance, which were also reflected in property and equipment as of December 31, 2020. All leasehold improvements will be depreciated over the remaining term of the lease.

The minimum annual rental payments of the Company's operating lease liability as of September 30, 2021 are as follows (in thousands):

	Amounts	
2021 (October through December)	$	114
2022		781
2023		965
2024		995
2025		1,024
Thereafter		2,794
Total minimum lease payments	$	6,673
Less: Amounts representing interest		(1,443)
Present value of future minimum lease payments	$	5,230
Current portion operating lease liability		306
Operating lease liability, noncurrent		4,924
Total operating lease liability	$	5,230

Straight-line rent expense recognized for operating leases was $171,000 and $516,000 for the three and nine months ended September 30, 2021, respectively, and $202,000 and $395,000 for the three and nine months ended September 30, 2020, respectively. There were no significant variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the three and nine months ended September 30, 2021 and 2020.

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The following information represents supplemental disclosure for the condensed statements of cash flows related to the Company's operating lease (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities		
Cash paid for amounts included in the measurement of lease liabilities	$ —	$ 144

The following summarizes additional information related to the operating lease:

	September 30, 2021
Weighted-average remaining lease term (in years)	6.8
Weighted-average discount rate	7.0 %

Manufacturing Agreements

The Company has entered into manufacturing supply agreements for the commercial supply of topical roflumilast cream which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $5.4 million within the next 3 months and then approximately $0.6 million per year for the following 4 years. This amount does not represent all of the Company's anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

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 the provisions of the Company's Bylaws and the Delaware General Corporation 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 any potential loss exposure under these indemnification agreements in excess of applicable insurance coverage is minimal.

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8. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

In connection with the Company's IPO in February 2020, all of the Company's outstanding shares of convertible preferred stock were automatically converted into 24,385,388 shares of common stock.

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. 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 September 30, 2021, no dividends had been declared by the board of directors.

The Company reserved the following shares of common stock for issuance as follows:

	September 30, 2021	December 31, 2020
Options issued and outstanding	5,715,147	3,655,945
Common stock awards available for grant under employee benefit plans	2,187,166	2,501,329
Restricted stock units outstanding	337,868	162,930
Total common stock reserved	8,240,181	6,320,204

Authorized Share Capital

On February 4, 2020, the Company's certificate of incorporation was amended and restated to provide for 300,000,000 authorized shares of common stock with a par value of $0.0001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.0001 per share. There were no shares of preferred stock outstanding as of September 30, 2021 and December 31, 2020.

9. Stock-Based Compensation

In January 2020, the Company's board of directors approved the 2020 Equity Incentive Plan (2020 Plan), which became effective January 30, 2020 in connection with the IPO. The 2020 Plan serves as the successor incentive award plan to the Company's 2017 Equity Incentive Plan (2017 Plan) and has 2,134,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock-based awards, plus 1,550,150 shares of common stock that were reserved for issuance pursuant to future awards under the 2017 Plan at the time the 2020 Plan became effective, plus shares represented by awards outstanding under the 2017 Plan that are forfeited or lapsed unexercised and which following the effective date of the 2020 Plan are not issued under the 2017 Plan. In addition, the 2020 Plan reserve will increase on January 1 of each year through 2030, by an amount equal to the lesser of (a) four percent of the shares of stock outstanding (on an as converted basis) on the day immediately prior to the date of increase and (b) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 11,000,000 shares of stock may be issued upon the exercise of incentive stock options. Accordingly, on January 1, 2021, the plan reserve increased by 1,747,112 shares. As of September 30, 2021, the Company had 1,456,234 shares available for future grant under the 2020 Plan.

The 2020 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 2020 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.

Following the Company's IPO and in connection with the effectiveness of the Company's 2020 Plan, the 2017 Plan terminated and no further awards will be granted under that plan. However, all outstanding awards under the 2017 Plan will continue to be governed by their existing terms.

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(unaudited)

Stock Option Activity

The following summarizes option activity (in thousands, except share amounts):

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2020	3,655,945	$ 12.09	8.78	$ 59,274
Granted	2,490,171	$ 28.04		
Exercised	(203,893)	$ 5.33		
Forfeited	(199,416)	$ 22.32		
Expired	(27,660)	$ 28.42		
Balance—September 30, 2021	5,715,147	$ 18.84	8.57	$ 44,093
Exercisable—September 30, 2021[1]	2,363,828	$ 10.28	7.66	$ 34,790

(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 fair value of the Company's common stock as of September 30, 2021. Prior to the Company's IPO in January 2020, the estimated fair value of the Company's common stock was determined by the board of directors.

The intrinsic value of options exercised for the nine months ended September 30, 2021 was $4.8 million.

The total grant-date fair value of the options vested during the nine months ended September 30, 2021 was $11.7 million. The weighted-average grant-date fair value of employee options granted during the nine months ended September 30, 2021 was $19.48.

Restricted Stock Unit Activity

The following table summarizes information regarding our RSUs:

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2020	162,930	$ 27.26
Granted	225,900	$ 30.51
Vested	(37,362)	$ 27.19
Forfeited	(13,600)	$ 31.37
Unvested Balance—September 30, 2021	337,868	$ 29.27

The grant date fair value of an RSU equals the closing price of our common stock on the grant date. RSUs generally vest equally over four years.

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Stock-Based Compensation Expense

Stock-based compensation expense included in the condensed statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 2,266	$ 1,067	$ 5,898	$ 2,209
General and administrative	3,097	1,194	12,308	3,091
Total stock-based compensation expense	$ 5,363	$ 2,261	$ 18,206	$ 5,300

As of September 30, 2021, there was $56.7 million of total unrecognized compensation cost related to unvested options that are expected to vest, which is expected to be recognized over a weighted-average period of 3.2 years. As of September 30, 2021, there was $7.9 million of total unrecognized compensation cost related to RSUs that is expected to vest, which is expected to be recognized over a weighted-average period of 3.2 years.

In March 2021, in connection with the retirement of the former Chief Financial Officer, the Company modified the terms of this individual's historical stock awards. As a result of the modifications, the Company recognized approximately $5.3 million of incremental stock compensation expense during the period, which is included in general and administrative expenses.

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—For options granted prior to IPO in the year ended December 31, 2019, 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. For options granted after IPO, the Company uses its closing stock price as reported on Nasdaq on the grant date for the fair value of its 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—The Company does not yet have sufficient trading history for its common stock to solely use its own historical volatility. Therefore, the expected volatility was estimated based on a combination of its own historical common stock volatility as well as 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.

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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, 2021	Year Ended December 31, 2020
Expected term (in years)	5.5 – 6.2	5.5 – 6.8
Expected volatility	80.6 – 85.2%	78.4 – 80.8%
Risk-free interest rate	0.6 – 1.1%	0.3 – 1.4%
Dividend yield	—%	—%

Early Exercise of Employee Options

The terms of the 2017 and 2020 Plans 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. While such shares have been issued, they are not considered outstanding for accounting purposes until they vest and are therefore excluded from shares used in determining 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 $110,000 and $258,000 as a liability from the early exercise in the accompanying condensed balance sheets as of September 30, 2021 and December 31, 2020, respectively. As of September 30, 2021 and December 31, 2020, there were $79,000 and $176,000 recorded in accrued liabilities, respectively, and $31,000 and $82,000 recorded in other long-term liabilities, respectively related to shares that were subject to repurchase.

Founder Awards

In August 2016, the Company issued 1,187,738 shares of restricted common stock to founders, of which 1,102,903 shares would vest under a service condition, and 84,835 shares would 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 were 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 were not considered outstanding for accounting purposes until they vested and are therefore excluded from shares used in determining loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. One-fourth of the 1,102,903 shares of restricted common stock were vested on the first-anniversary date and the remaining 827,177 shares vested on a monthly basis thereafter. All shares of restricted stock subject to the award were vested as of June 30, 2020.

2020 Employee Stock Purchase Plan

The Company adopted the 2020 Employee Stock Purchase Plan, or the ESPP, which became effective on January 30, 2020 in connection with the IPO. The ESPP is designed to allow the Company's eligible employees to purchase shares of the Company's common stock, at semi-annual intervals, with their accumulated payroll deductions. Under the ESPP, participants are offered the option to purchase shares of the Company's common stock at a discount during a series of successive offering periods. The option purchase price will be the lower of 85% of the closing trading price per share of the Company's common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period.

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The ESPP is intended to qualify under Section 423 of the U.S. Internal Revenue Service Code of 1986, as amended. The maximum number of the Company's common stock which will be authorized for sale under the ESPP is equal to the sum of (a) 351,000 shares of common stock and (b) an annual increase on the first day of each year beginning in 2021 and ending in 2030, equal to the lesser of (i) 1% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors; provided, however, no more than 5,265,000 shares of the Company's common stock may be issued under the ESPP. Accordingly, on January 1, 2021, the ESPP reserve increased by 436,778 shares.

The Company commenced an offering period on January 31, 2020, which ended on May 31, 2020, and resulted in 19,862 shares of stock being issued under the ESPP. The Company also commenced an offering period on June 1, 2020, which ended on November 30, 2020, and resulted in 14,326 shares of stock being issued under the ESPP. In addition, the Company commenced an offering period on December 1, 2020, which ended on May 31, 2021, and resulted in 22,658 shares of stock being issued under the ESPP. Stock-based compensation expense related to the ESPP was $88,000 and $304,000 for the three and nine months ended September 30, 2021, respectively, and $88,000 and $249,000 for the three and nine months ended September 30, 2020, respectively.

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:

	As of September 30,	
	2021	2020
Stock options to purchase common stock	5,715,147	3,604,363
Early exercised options subject to future vesting	131,923	419,312
RSU's subject to future vesting	337,868	163,560
ESPP shares subject to future issuance	22,634	14,817
Total	6,207,572	4,202,052

Item 2. 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 unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto as of and for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2020, which has been filed with the Securities and Exchange Commission (SEC). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans, objectives, expectations, projections, and strategy for our business, includes forward-looking statements that involve risks and uncertainties. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties, and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. As a result of many factors, including those factors identified below and those set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results and the timing of selected events could differ materially from the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions. Our current portfolio is comprised of highly differentiated topical treatments with significant potential to treat immune-mediated dermatological diseases and conditions. We believe we have built the industry's leading platform for dermatologic product development. Our strategy is to focus on validated biological targets, and to use our platform and deep dermatology expertise to develop differentiated products that have the potential to address the 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.

In September 2021, we submitted a New Drug Application (NDA) to the FDA for our lead product candidate, roflumilast cream, for the treatment of mild-to-severe plaque psoriasis. Roflumilast cream is a once-daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor. PDE4 is an established biological target in dermatology, with multiple PDE4 inhibitors approved by the FDA for dermatological conditions. We are developing roflumilast cream for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. We have also successfully completed a long-term safety study of roflumilast cream in plaque psoriasis patients.

Additionally, we have completed a Phase 2 proof of concept study of roflumilast cream in atopic dermatitis, and enrollment is underway in pivotal Phase 3 clinical trials, with topline data expected in the second half of 2022.

We are also developing a topical foam formulation of roflumilast, and have successfully completed Phase 2 studies in both seborrheic dermatitis and scalp and body psoriasis. Enrollment is underway in single pivotal Phase 3 clinical trials in each of the seborrheic dermatitis and scalp and body psoriasis indications. Topline data is expected in the second or third quarter of 2022 for seborrheic dermatitis and the second half of 2022 for scalp and body psoriasis. If successful, we believe these studies will be sufficient bases to file for regulatory approval, based on our discussions with the FDA.

We are developing ARQ-252, a potent and highly selective topical JAK1 inhibitor, for the treatment of chronic hand eczema and vitiligo. As previously disclosed, our Phase 1/2b study of ARQ-252 for the treatment of chronic hand eczema did not meet its primary endpoint. Further analyses of that study pointed toward inadequate local drug delivery to the skin as a key driver of the lack of efficacy. Importantly, there were no safety or tolerability issues seen in that study. Based on these findings, we also terminated our Phase 2 proof of concept study evaluating ARQ-252 as a potential treatment for vitiligo. We are currently working on re-formulating ARQ-252 to develop an enhanced formulation that delivers more active drug to targets in the skin.

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.

Since our inception in 2016, we have invested a significant portion of our efforts and financial resources in clinical development activities. We have not generated any revenue from product sales and have funded our operations primarily with the net proceeds from our IPO completed in January 2020 and with the net proceeds from our follow-on equity offerings in October 2020 and February 2021, respectively, as well as with $162.5 million in net cash proceeds from private placements of our convertible preferred stock prior to IPO. On February 4, 2020, we closed our IPO of 10,781,250 shares of common stock at an offering price of $17.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 1,406,250 additional shares of common stock. Our net proceeds, after deducting underwriting discounts, commissions, and offering related transaction costs, were $167.2 million. In addition, on October 6, 2020, we closed our public offering of 4,000,000 shares of common stock and concurrent private placement of 1,400,000 shares of common stock, both at a price of $25.00 per share, receiving an aggregate of $128.4 million in net proceeds after deducting the underwriting discounts, commissions, and offering related transaction costs. Also, on February 5, 2021, we closed our public offering of 6,325,000 shares of common stock at a price of $35.00 per share, including 825,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, receiving an aggregate of $207.5 million in net proceeds, after deducting underwriting discounts, commissions, and offering related transaction costs. See Note 1 to the unaudited condensed financial statements for additional information.

We have incurred net losses in each year since inception, including net losses of $57.0 million and $135.0 million for the three and nine months ended September 30, 2021, respectively, and $38.2 million and $101.6 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $337.0 million and cash, cash equivalents, restricted cash, and marketable securities of $368.8 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. 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 for additional information. Based on our current planned operations, we expect that our current cash, cash equivalents, and marketable securities will be sufficient to fund our operations well into 2023.

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 fully developed commercial infrastructure. Accordingly, we expect to incur significant expenses to fully develop a sales organization or commercial infrastructure in advance of generating any product sales.

COVID-19 Update

In March 2020, the World Health Organization declared a pandemic related to the COVID-19 outbreak. COVID-19 has placed strains on the providers of healthcare services, including the sites where we conduct our clinical trials. These strains have resulted in some clinical sites slowing or halting enrollment in clinical trials and restricting the on-site monitoring of clinical trials. We follow FDA guidance on clinical trial conduct during the COVID-19 pandemic, including the remote monitoring of clinical data. We are monitoring the impact COVID-19 may have on the clinical development of our product candidates, including potential delays or modifications to ongoing and planned trials. Thus far, we have seen limited impact on our clinical trials, including some disruptions in screening, enrollment, and monitoring; however at this time, we do not expect delays to previously disclosed clinical timelines, including those for roflumilast cream and roflumilast foam. We cannot, at this time, predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on our ongoing and planned clinical trials and other business operations.

There have been no disruptions in our supply chain of drug manufacturers necessary to conduct our clinical trials and, given our drug inventories, we believe that we will be able to supply the drug needs of our ongoing clinical studies.

In alignment with public health guidance designed to slow the spread of COVID-19, we implemented a remote work plan for all employees as of mid-March 2020. We developed a return-to-work protocol, and as the pandemic conditions improved in the southern California region, we reopened our office for in-person work beginning in the first quarter of 2021, and have now returned to normal operations. We may need to undertake additional actions that could impact our operations as required by applicable laws or regulations, or which we determine to be in the best interests of our employees.

License Agreements

AstraZeneca License Agreement

In July 2018, we entered into 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 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 484,388 shares of our Series B Preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product. We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specific regulatory approval milestones with respect to the AZ-Licensed Products, which includes $7.5 million upon FDA approval of our first product, 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. See Note 6 to the unaudited condensed financial statements for additional information.

Hengrui Exclusive Option and License Agreement

In January 2018, we entered into the 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 1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Canada, Japan, and the European Union (including for clarity the United Kingdom). We made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui Option and License Agreement. In December 2019, we exercised our exclusive option under the agreement, for which we made a $1.5 million cash payment, and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, 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.

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. See Note 6 to the unaudited condensed financial statements for additional information.

Components of Our Results of Operations

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 on a program specific basis (topical roflumilast program, topical JAK inhibitor program, and early stage programs). Our internal costs are primarily related to personnel or professional services and apply across programs, and thus are not allocatable on a program specific basis.

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 roflumilast cream for atopic dermatitis, the Phase 3 trials of roflumilast foam for seborrheic dermatitis and scalp and body psoriasis, ARQ-252 for chronic 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 roflumilast cream, roflumilast foam, 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 the development of our product candidates.

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, insurance, and professional services fees for marketing, 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, insurance, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors and officers liability insurance premiums, and investor relations activities.

Other Income, Net

Other income, net primarily consists of interest income earned on our cash, cash equivalents, and marketable securities.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

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

	Three Months Ended September 30,		Change	
	2021	2020	$	%
	(unaudited) (in thousands)			
Operating expenses:				
Research and development	$ 40,604	$ 32,743	$ 7,861	24 %
General and administrative	16,474	5,560	10,914	196 %
Total operating expenses	$ 57,078	$ 38,303	$ 18,775	49 %
Loss from operations	(57,078)	(38,303)	(18,775)	49 %
Other income, net	98	99	(1)	(1) %
Net loss	$ (56,980)	$ (38,204)	$ (18,776)	49 %

Research and Development Expenses

	Three Months Ended September 30,		Change	
	2021	2020	$	%
	(unaudited) (in thousands)			
Direct external costs:				
Topical roflumilast program	$ 26,743	$ 24,146	$ 2,597	11 %
Topical JAK inhibitor program	955	4,172	(3,217)	(77) %
Other early stage programs	178	39	139	356 %
Indirect costs:				
Compensation and personnel-related	8,436	3,664	4,772	130 %
Other	4,292	722	3,570	494 %
Total research and development expense	$ 40,604	$ 32,743	$ 7,861	24 %

Research and development expenses increased by $7.9 million, or 24%, for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The increase was primarily due to an increase in compensation and personnel-related costs of $4.8 million, an increase in other costs of $3.6 million, and an increase in direct costs related to the topical roflumilast program of $2.6 million. These increases were partially offset by a decrease in direct costs related to the topical JAK inhibitor program (ARQ-252 and ARQ-255) of $3.2 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount to manage our growing clinical programs. The increase in other costs was primarily due to an increase in consulting activity and medical affairs spending. The increase in topical roflumilast program costs was primarily due to increased manufacturing costs offset by a slight decrease in clinical trial costs. Clinical trial costs declined due to the completion of Phase 3 studies of roflumilast cream in plaque psoriasis, partially offset by the initiation of Phase 3 studies of roflumilast cream in atopic dermatitis and Phase 3 studies of roflumilast foam in seborrheic dermatitis and scalp psoriasis. The decrease in topical JAK inhibitor program costs was primarily due to the completion of our Phase 2 study of ARQ-252 in chronic hand eczema.

General and Administrative Expenses

General and administrative expenses increased by $10.9 million, or 196%, for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The increase was primarily due to an increase in compensation and personnel-related expenses of $6.9 million, and an increase in professional services of $3.1 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount. The increase in professional services was due to an increase in consulting activity and marketing expenses primarily related to roflumilast.

Other Income, Net

Other income, net decreased by $1,000, or 1%, for the three months ended September 30, 2021 compared to the three months ended September 30, 2020.

Comparison of the Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30,		Change	
	2021	2020	$	%
	(unaudited) (in thousands)			
Operating expenses:				
Research and development	$ 93,000	$ 87,934	$ 5,066	6 %
General and administrative	42,243	14,647	27,596	188 %
Total operating expenses	$ 135,243	$ 102,581	$ 32,662	32 %
Loss from operations	(135,243)	(102,581)	(32,662)	32 %
Other income, net	213	952	(739)	(78) %
Net loss	$ (135,030)	$ (101,629)	$ (33,401)	33 %

Research and Development Expenses

	Nine Months Ended September 30,		Change	
	2021	2020	$	%
	(unaudited) (in thousands)			
Direct external costs:				
Topical roflumilast program	$ 53,416	$ 67,980	$ (14,564)	(21) %
Topical JAK inhibitor program	8,470	7,785	685	9 %
Other early stage programs	434	76	358	471 %
Indirect costs:				
Compensation and personnel-related	19,874	9,040	10,834	120 %
Other	10,806	3,053	7,753	254 %
Total research and development expense	$ 93,000	$ 87,934	$ 5,066	6 %

Research and development expenses increased by $5.1 million, or 6%, for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The increase was primarily due to an increase in compensation and personnel-related costs of $10.8 million, an increase in other costs of $7.8 million, and an increase in direct costs related to the topical JAK inhibitor program of $0.7 million. These increases were partially offset by a decrease in direct costs related to the topical roflumilast program of $14.6 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount to manage our growing clinical programs. The increase in other costs were primarily due to an increase in consulting activity and medical affairs spending. The increase in topical JAK inhibitor program costs were primarily due to our Phase 2 study of ARQ-252 in vitiligo, partially offset by lower costs related to our Phase 2 study of ARQ-252 in chronic hand eczema. The decrease in topical roflumilast program costs relate primarily to the completion of the Phase 3 studies of roflumilast cream for plaque psoriasis and the Phase 2 studies of roflumilast foam in seborrheic dermatitis and scalp and body psoriasis. This decrease was partially offset by the costs related to our Phase 3 studies of roflumilast cream in atopic dermatitis and Phase 3 studies of roflumilast foam in seborrheic dermatitis and scalp and body psoriasis.

General and Administrative Expenses

General and administrative expenses increased by $27.6 million, or 188%, for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The increase was primarily due to an increase in compensation and personnel-related expenses of $18.1 million, and an increase in professional services of $7.8 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was due to an increase in headcount, coupled with the recognition of $5.3 million of incremental stock-based compensation expense as a result of modification to the vesting schedule and exercise term of previously-granted awards in connection with the retirement of our former Chief Financial Officer during the first quarter. The increase in professional services was mainly due to an increase in consulting activity and marketing expenses primarily related to roflumilast.

Other Income, Net

Other income, net decreased by $0.7 million, or 78%, for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The decrease was due to a lower yield on our investment portfolio.

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, 2021, we had cash, cash equivalents, restricted cash, and marketable securities of $368.8 million, and an accumulated deficit of $337.0 million. We anticipate that operating losses and net cash used in operating activities will increase over the next several years as we further develop roflumilast cream, roflumilast foam, 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, as well as our IPO completed in January 2020, and our follow-on financings in October 2020 and February 2021. We will continue to be dependent upon equity, debt financing, collaborations, or other forms of capital at least until we are able to generate positive cash flows from our operations. On May 6, 2021, we entered into a Sales Agreement, with Cowen, to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $100.0 million through an ATM equity offering program under which Cowen acts as sales agent. During the nine months ended September 30, 2021, we did not issue or sell any shares of our common stock through our ATM.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
	(unaudited)	
	(in thousands)	
Cash used in operating activities	$ (122,918)	$ (80,462)
Cash used in investing activities	(99,452)	(105,932)
Cash provided by financing activities	209,066	168,765
Net decrease in cash, cash equivalents, and restricted cash	$ (13,304)	$ (17,629)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2021, net cash used in operating activities was $122.9 million, which consisted of a net loss of $135.0 million and a change in net operating assets and liabilities of $9.2 million, partially offset by net non-cash charges of $21.3 million. The change in net operating assets and liabilities was primarily due to an increase of $6.1 million in prepaid expenses and other current assets and a decrease of $3.4 million in accounts payable and accrued liabilities due to the timing of payments and lower outstanding accounts payable balances for our contract research organizations (CROs). The net non-cash charges were primarily related to stock-based compensation expense of $18.2 million.

During the nine months ended September 30, 2020, net cash used in operating activities was $80.5 million, which consisted of a net loss of $101.6 million, offset by a change in net operating assets and liabilities of $15.9 million and net non-cash charges of $5.3 million. The change in net operating assets and liabilities was primarily due to an increase of $16.3 million in accounts payable and accrued liabilities due to our operating expense growth and timing of payments. The net non-cash charges were primarily related to stock-based compensation expense of $5.3 million.

Net Cash Used in Investing Activities

During the nine months ended September 30, 2021, net cash used in investing activities was $99.5 million, which was comprised primarily of purchases of marketable securities of $244.3 million, partially offset by the proceeds from the maturities of marketable securities of $145.6 million.

During the nine months ended September 30, 2020, net cash used in investing activities was $105.9 million, which was comprised primarily of purchases of marketable securities of $179.4 million, partially offset by proceeds from the maturities of marketable securities of $73.6 million.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2021, net cash provided by financing activities was $209.1 million, which was comprised primarily of the net cash proceeds received from the follow-on financing in February 2021 of $207.5 million.

During the nine months ended September 30, 2020, net cash provided by financing activities was $168.8 million, which was comprised primarily of the net cash proceeds received from the IPO of $168.6 million.

Funding Requirements

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $337.0 million as of September 30, 2021. We had cash, cash equivalents, and marketable securities of $367.3 million as of September 30, 2021. Based on our current planned operations, we expect that our current cash, cash equivalents, and marketable securities will be sufficient to fund our operations well into 2023. 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 or ongoing clinical studies of roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast foam in seborrheic dermatitis and scalp and body psoriasis, ARQ-252 in chronic hand eczema and vitiligo, and our formulation and preclinical efforts for ARQ-255 for alopecia areata;
- suspensions or delays in the enrollment or changes to the number of patients we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic;
- 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

The following summarizes our significant contractual obligations as of September 30, 2021.

Facility Operating Lease

In April 2020, we amended our lease agreement for our facility in Westlake Village, California to relocate to a new expanded space including 22,643 square feet. The lease payment term for the new space began on December 30, 2020 and will terminate 91 months thereafter, with a renewal option term of five years. We have a one-time option to cancel the lease after month 67.

The lease is subject to fixed rate escalation increases with an initial base rent of $76,000 per month and includes rent free periods aggregating approximately one year. The amended lease agreement required that we deliver a letter of credit to the landlord of $1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, in November 2020, we entered into a letter of credit for $1.5 million, which is secured with a restricted cash account in the same amount. The total commitment under the operating lease agreement is $6.7 million, including $0.1 million for the remaining three months of 2021, $0.8 million for 2022, $1.0 million for each of the years 2023, 2024 and 2025, and $2.8 million for 2026 and thereafter. See Note 7 to the unaudited condensed financial statements for additional information.

Manufacturing Agreements

We have entered into manufacturing supply agreements for the commercial supply of topical roflumilast cream which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $5.4 million within the next 3 months and then approximately $0.6 million per year for the following 4 years. This amount does not represent all of the our anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

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

The preparation of our condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2020. There were no material changes to our critical accounting policies during the nine months ended September 30, 2021.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed financial statements.

Emerging Growth Company Status

We are an emerging growth company as defined in 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 No. 016-01, *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*, ASU No. 2016-02, *Leases,* ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* and ASU No. 2019-12, *Income Taxes (Topic 740),* 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 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. As of June 30, 2021, we determined that we will become a "large accelerated filer" under the rules of the SEC and we will no longer be classified as an emerging growth company as of December 31, 2021.

Item 3. 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, 2021, we had cash and cash equivalents of $51.8 million, restricted cash of $1.5 million, and marketable securities of $315.5 million; which consist of bank deposits, money market funds, commercial paper, government securities, and corporate debt 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, 2021.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized, and reported, within the time periods specified in the SEC’s rules and forms. There is no assurance that our disclosure controls and procedures will operate effectively under all circumstances.

Management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term “disclosure controls and procedures,” as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our CEO and CFO have concluded that, as of September 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the nine months ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

We may from time to time be involved in various legal proceedings of a character normally incident to the ordinary course of our business. We are not currently a party to any material litigation or other material legal proceedings.

Item 1A. RISK *FACTORS*

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition, and the trading price of our common stock. This discussion should be read in conjunction with the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", and our Annual Report on Form 10-K for the year ended December 31, 2020. 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. 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 late-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 late-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 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 nine months ended September 30, 2021 was approximately $135.0 million. As of September 30, 2021, we had an accumulated deficit of $337.0 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 (deficit) 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.

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, roflumilast cream, roflumilast foam, 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, 2021, we had capital resources consisting of cash, cash equivalents, and marketable securities of $367.3 million. Based on our planned operations, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operations well into 2023. 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 or ongoing clinical studies of roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast foam in seborrheic dermatitis and scalp and body psoriasis, ARQ-252 in chronic hand eczema and vitiligo, and our formulation and preclinical efforts for ARQ-255 in alopecia areata;
- suspensions or delays in the enrollment, issues with data collection, or changes to the number of patients we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic;
- 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, and any discounts or rebates to channel to obtain access;
- 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, 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;
- 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 roflumilast cream, 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, especially in light of the COVID-19 pandemic;
- 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. 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;
- the willingness of patients to pay out-of-pocket for our product candidates, if approved, in the absence of health insurance coverage or sufficient reimbursement;
- 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 there can be no assurance as to 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q should not be taken as indicative of our ability to grow our business.

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 roflumilast cream, a potent PDE4 inhibitor topical cream for the treatment of plaque psoriasis and atopic dermatitis, and our additional product candidates roflumilast foam, a topical foam formulation of roflumilast for the treatment of scalp and body psoriasis and seborrheic dermatitis, ARQ-252, a potent and highly selective topical JAK1 inhibitor for the treatment of chronic hand eczema and vitiligo, and ARQ-255, a potential topical treatment for alopecia areata. We currently do not have drug discovery efforts, and we have no intention to develop these. 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 our current product candidates. We expect to conduct most of our clinical trials in the United States and Canada, with currently limited plans for clinical trials in Australia, the Caribbean, and the EU. 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 develop, 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, particularly as a result of the impact of the COVID-19 pandemic, 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 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. For example, our Phase 2 proof of concept study in atopic dermatitis had a limited number of patients and did not reach statistical significance for the primary endpoint of absolute change in Eczema and Severity Index (EASI). However, this study did provide evidence that roflumilast cream could provide symptomatic improvement, with statistically significant difference from vehicle on several key secondary endpoints, and a favorable tolerability profile in adults with atopic dermatitis and, following an End of Phase 2 meeting with the FDA in September 2020, we omitted our previously planned Phase 2b study in that indication and recently initiated Phase 3 clinical trials. Additionally, our Phase 1/2b clinical study of ARQ-252 for the treatment of chronic hand eczema did not meet its primary end point of IGA clear or almost clear at week 12 and we terminated our Phase 2a clinical trial evaluating ARQ-252 as a potential treatment for vitiligo. 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.

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:

- clinical site closures, delays to patient enrollment, subjects discontinuing treatment or follow-up visits, issues with data collection, or changes to trial protocols as a result of the COVID-19 pandemic;
- regulators or independent institutional review boards (IRBs) 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 IRBs 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 IRBs 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 IRBs 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 efficacy of the product for the intended indication applied for in the applicable regulatory filing. Product development is a long, expensive, and uncertain process, 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.

We currently have no products approved for sale; in September we submitted our first NDA to the FDA for our lead product candidate, topical roflumilast cream, and our other product candidates remain in clinical development. Significant risk remains and we cannot provide assurance that they will obtain regulatory approval for commercialization as expected, or at all. 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 EU.

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 Phase 3 clinical trials of roflumilast cream 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 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 (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;
- 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 are 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 Phase 3 clinical trials of roflumilast cream in plaque psoriasis, and our previous and planned clinical trials in atopic dermatitis, vitiligo, chronic hand eczema, scalp and body psoriasis and seborrheic dermatitis 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 WI-NRS 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.

The use of patient reported outcome instruments in our Phase 3 clinical trials of roflumilast cream 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 roflumilast cream in plaque psoriasis and atopic dermatitis as well as our Phase 3 clinical trials of roflumilast foam in seborrheic dermatitis and scalp and body 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 IGA scale, referred to as IGA Success. Success in our clinical trials with these or similar endpoints, requires the enrollment of patients with conditions that are severe enough to facilitate a 2-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 clinical trials will produce the same statistically significant results in IGA Success, which will serve as the primary endpoint, as our prior clinical trials, and there can be no guarantee that the characteristics of the population enrolled in our clinical trials, including 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 roflumilast cream 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 roflumilast cream, roflumilast foam, 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 IRB, 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 REMS;
- we may be required to conduct Phase 4 clinical trials as post-marketing requirements;
- 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.

As a company, we have never 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.

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 limited experience doing so. As a result, the approval process and related 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 submitted an NDA and have completed two Phase 3 studies and three Phase 2 studies in plaque psoriasis with roflumilast cream, a Phase 2 study in atopic dermatitis with roflumilast cream, and two Phase 2 studies in seborrheic dermatitis and scalp and body psoriasis with roflumilast foam. We have also recently initiated pivotal Phase 3 clinical trials of roflumilast cream for the treatment of atopic dermatitis and of roflumilast foam in seborrheic dermatitis and scalp and body psoriasis. 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. While the FDA encouraged us at our atopic dermatitis End of Phase 2 meeting to generate additional clinical data in adolescents and adults on the two roflumilast cream doses studied in our Phase 2 study, they also did not raise objections to us proceeding into Phase 3. 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 (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;
- the willingness of patients to pay out-of-pocket for our product candidates, if approved, in the absence of health insurance coverage or sufficient reimbursement;
- 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.

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 limited 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 to build a significantly more robust sales and marketing organization. We currently have limited 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.

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 roflumilast cream in the United States, but prior to commencement of commercialization or sales of roflumilast cream, we will be required to make certain milestone payments to AstraZeneca. We paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product (as defined below). We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specified 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.

In connection with the exercise of our exclusive option with Hengrui in December 2019, we made a $1.5 million cash payment and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, 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 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, chronic 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. and Pfizer Inc.; non-injectable systemic therapies used to treat plaque psoriasis such as Otezla, marketed by Amgen Inc.; topical therapies such as branded and generic versions of clobetasol, such as Clobex, marketed by Galderma Laboratories, LP, generic versions of calcipotriene and the combination of betamethasone dipropionate/calcipotriene; 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 roflumilast cream, including topical tapinarof, under development by Dermavant Sciences, Inc., deucravacitinib, an oral Tyk2 inhibitor under development by BMS, Inc., and PF-06700841, an oral Tyk2/JAK1 inhibitor under development by Pfizer, Inc.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., Opzelura, marketed by Incyte Corporation, 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 roflumilast cream, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc., topical PF-06700841, a Tyk2/JAK1 inhibitor under development by Pfizer, Inc., topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, oral PF-04965842, under development by Pfizer Inc., oral upatacitinib, under development by AbbVie, Inc., and injectable lebrikizumab, under development by Eli Lilly and Company.

For chronic 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 chronic hand eczema that would compete with ARQ-252 is delgocitinib, which recently showed proof of concept in a Phase 2a trial and has been approved in a different formulation in Japan (Corectim).

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 oral PF-06651600 and oral PF-06700841, 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: topical PF-06700841 and oral PF-06651600, under development by Pfizer, Inc., oral CTP-543, under development by Concert Pharmaceuticals, and oral 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 September 30, 2021, we had 143 full-time employees. We will need to continue to expand our managerial, clinical, commercial, operational, financial, 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.

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:

- 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;
- 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; 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, financial, 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 efforts, but rather we intend to formulate, 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.

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 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 sales, 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 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 incur significant costs as a result of operating as a public company, and our management devotes 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 have incurred and will continue to 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, or the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the 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 devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations increase our legal and financial compliance costs and 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.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 (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. 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, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. As of June 30, 2021, we determined that we will become a "large accelerated filer" under the rules of the SEC and we will no longer be classified as an emerging growth company as of December 31, 2021. Once we are no longer an emerging growth company 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.

During the course of our review and testing of our internal controls over financial reporting, 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 are 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.

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 (and other similar non-U.S. laws), if applicable, including HIPAA, as amended by HITECH, and regulations implemented thereunder, 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, 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 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 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. Business changes at any of these manufacturers, or their failure to provide us with sufficient quantities at acceptable quality levels, or at all, would materially and adversely affect our business.

We do not currently have 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 have successfully manufactured and tested several batches of our topical roflumilast product candidates at our primary commercial contract manufacturing site at the initial commercial scale. However, as a late-stage company with no prior history of product sales or commercialization of products, representative batches of our product candidate received to date may not represent what will be required to meet our future commercial requirements or be manufactured at final commercial scale.

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. If there is a disruption to one or more of our third-party suppliers' relevant operations, we will have no other means of producing our lead product candidates until the affected facilities are restored or alternative manufacturing facilities or sources of supply are procured. 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 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 either we or our manufacturers 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 roflumilast cream, ARQ-154 roflumilast foam, ARQ-252, or ARQ-255, the processes and systems used in their manufacture 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 have very limited control over the day-to-day 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, roflumilast cream, roflumilast foam, 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 roflumilast cream, roflumilast foam, 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 roflumilast cream, roflumilast foam, 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. Furthermore, external events such as the COVID-19 pandemic could interfere with some operations of these CROs.

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 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 with 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, 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 roflumilast cream and roflumilast foam with claims directed to, among other things, formulating roflumilast in combination with hexylene glycol and pharmacokinetic properties of topical roflumilast for improving delivery and extending half-life are currently projected to expire on June 7, 2037 and August 25, 2037, and the issued U.S. patents which we have exclusive rights to from Hengrui as a result of the exercise of our exclusive option with Hengrui in December 2019 for the amount of $1.5 million cash, related to the composition of matter of the active ingredient in ARQ-252 and ARQ-255 (or bisulfate or crystal forms thereof) are currently projected to expire between January 21, 2033 and October 15, 2035 unless a PTE 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 roflumilast cream, roflumilast foam, 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 roflumilast cream, roflumilast foam, 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 roflumilast cream, roflumilast foam, 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 roflumilast cream, roflumilast foam, 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 U.S. Patent and Trademark Office (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 roflumilast cream, roflumilast foam, ARQ-252, or ARQ-255 can be challenged by competitors.

If roflumilast cream, roflumilast foam, ARQ-252, or ARQ-255 is approved by the FDA, one or more third parties may challenge the patents covering roflumilast cream, roflumilast foam, 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 NDA, or ANDA, for a generic drug bioequivalent to roflumilast cream, roflumilast foam, 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 roflumilast cream and pharmacokinetic properties of topical roflumilast for improving delivery and extending half-life are currently projected to expire on June 7, 2037 and August 25, 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 (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 nonexclusive 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.

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 will require final regulatory approval of, and registered trademarks for, any commercial tradename and registered trademarks for a commercial trade name for our lead candidates in the United States or foreign jurisdictions and failure to secure such approval in a timely fashion could adversely affect our business.

We have received Notices of Allowance from the USPTO for commercial trade names for certain of our lead product candidates in the United States. We will be required to obtain similar approvals in certain foreign jurisdictions and will be required to undertake similar registrations with respect to any future product candidates. During trademark registration proceedings, we may receive rejections and 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. While we have received Notices of Allowance from the USPTO for commercial trade names for certain of our lead product candidates, we have not received final FDA approval of such names. If the FDA objects to any of our proposed 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.

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 roflumilast cream, roflumilast foam, ARQ-252, and ARQ-255, which could include requirements for a medication guide, physician communication plans, or additional ETASU, 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. The policies of the FDA and of other regulatory authorities may change and additional governmental regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. For example, certain policies of the new U.S. administration may impact our business and industry. Namely, the previous U.S. administration took 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 or whether these executive actions, including the Executive Orders, will be implemented, or whether they will be rescinded or replaced by the new U.S. administration. Certain policies of U.S. presidential administrations may impact our business and industry, and changing presidential administrations may result in the issuance of Executive Orders that could impact our business, regulatory environment, and industry. It is difficult to predict how such requirements, Executive Orders, and policies will be implemented.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns 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. Average review times at the agency have fluctuated in recent years as a result. 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 adversely affect 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 have a material adverse effect on our business.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on 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.
- 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. 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;
- 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;
- 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, the ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, manufacturers will also be required to report payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives during the previous year;
- 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; and 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.

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 ACA, as amended by the Health Care and Education Reconciliation Act, collectively the ACA, 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 ACA 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, the Tax Cuts and Jobs Act of 2017, or TCJA, was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas (Texas District Court Judge) ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal, or replace the ACA will impact the law or our business. It is also unclear how other efforts, if any, to challenge, repeal, or replace the ACA will impact the ACA our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021; 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 ACA, 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 be subject to enforcement action and we may not achieve or sustain profitability, which would adversely affect our business.

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.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal, and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act (CCPA) on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA 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. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Risks Related to Our Common Stock

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." As of June 30, 2021, we determined that we will become a "large accelerated filer" under the rules of the SEC and we will no longer be classified as an emerging growth company as of December 31, 2021.

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 of 1933, as amended, or 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.

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.

On May 6, 2021, we entered into a sales agreement, or Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $100,000,000, through an ATM equity offering program under which Cowen will act as our sales agent. During the nine months ended September 30, 2021, we did not issue or sell any shares of our common stock through our ATM Offering Program. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. 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. Moreover, holders of approximately 25.8 million shares of our common stock (including 1.4 million shares issued and sold pursuant to the private placement of shares in

connection with our follow-on financing) have rights, subject to certain 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 other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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.

Our ability to utilize our Net Operating Loss carryforwards and research and development income tax credit carryforwards may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. We have NOL carryforwards available to reduce future taxable income, if any, for federal, California and other state income tax purposes. If not utilized, state NOL carryforwards will expire beginning in 2030. A small amount of our federal NOL that was originated before the 2018 tax year will expire beginning in 2036. Under the Tax Act and Jobs Act of 2017, the remaining amount of our federal NOL carryforwards generated after December 31, 2017 will carryforward 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 our IPO (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.

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 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 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.

Our restated certificate of incorporation provides 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.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides 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, 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.

General Risk Factors

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. For example, outbreaks of epidemic, pandemic, or contagious diseases, such as the COVID-19 outbreak, could disrupt our business. Business disruptions could include disruptions to the enrollment, clinical site availability, patient accessibility and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, the COVID-19 outbreak, including developments involving subsequent COVID-19 variants, may result in a severe economic downturn and has already significantly affected the financial markets of many countries. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise 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.

The stock price of our common stock may be volatile or may decline.

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 we discontinue development or if 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, legal or political 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, including as a result of market volatility related to global health concerns and, in particular, the extreme volatility experienced during the ongoing COVID-19 pandemic;
- 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 Annual Report on Form 10-K.

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. Due to the COVID-19 outbreak, there has been significant stock market exchange volatility, including temporary trading halts. 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 only recently completed our IPO and just recently obtained research coverage by securities and industry analysts. If only a limited number of securities or industry analysts commence coverage of us or the few analysts that have initiated coverage, drop coverage, the trading price for our stock would be negatively impacted. 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.

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, our Chief Technical Officer, David W. Osborne, Ph.D, and our Chief Medical Officer, Patrick Burnett, M.D., 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 and restricted stock units (RSUs) that vest over time. The value to employees of stock options and RSUs 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.

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, including an epidemic, pandemic or contagious disease outbreak such as COVID-19 that disrupted operations, we may experience difficulties in operating 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.

Future litigation could have a material adverse effect on our business and results of operations.

Lawsuits and other administrative or legal proceedings, including intellectual property litigation or other legal proceedings relating to intellectual property claims, that may arise in the course of our operations can involve substantial costs, including the costs associated with investigation, litigation and possible settlement, judgment, penalty or fine. In addition, lawsuits and other legal proceedings may be time-consuming to defend or prosecute and may require a commitment of management and personnel resources that will be diverted from our normal business operations. Although we generally maintain insurance to mitigate certain costs, there can be no assurance that costs associated with lawsuits or other legal proceedings will not exceed the limits of insurance policies. Moreover, we may be unable to continue to maintain our existing insurance at a reasonable cost, if at all, or to secure additional coverage, which may result in costs associated with lawsuits and other legal proceedings being uninsured. Our business, financial condition and results of operations could be adversely affected if a judgment, settlement penalty or fine is not fully covered by insurance.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Use of Proceeds

There has been no material change in the planned use of proceeds from our IPO from that described in the related prospectus dated January 30, 2020, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

None.

Item 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document	Incorporated by Reference Form	Date	Number	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation.	10-Q	5/12/20	3.1	
3.2	Restated Bylaws.	10-Q	5/12/20	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	1/21/20	4.1	
4.2†	Amended and Restated Investors' Rights Agreement, dated October 8, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	1/21/20	4.2	
4.3	Description of Arcutis Biotherapeutics' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	3/19/20	4.3	
10.1†	Supply and Manufacturing Agreement, dated September 15, 2021, between DPT Laboratories, Ltd. and the Registrant.				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of Arcutis Biopharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

ARCUTIS BIOTHERAPEUTICS, INC.

Date: November 04, 2021

By: /s/ Todd Franklin Watanabe

Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 04, 2021

By: /s/ Scott L. Burrows

Scott L. Burrows
Chief Financial Officer
(Principal Financial and Accounting Officer)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is the type that the registrant treats as private or confidential and is not material.

SUPPLY AND MANUFACTURING AGREEMENT

This Supply and Manufacturing Agreement (the "**Agreement**") is made as of this 15th day of September 2021 (the "**Effective Date**") by and between DPT Laboratories, Ltd., a Texas Limited Partnership with a place of business at 307 East Josephine Street, San Antonio, Texas 78215 (hereinafter "**DPT**") and Arcutis Biotherapeutics, Inc., a Delaware corporation having principal offices at 3027 Townsgate Road, Suite 300, Westlake Village, California 91361 ("**COMPANY**"). COMPANY and DPT may be referred to herein by name or individually, as a "**Party**" and collectively, as the "**Parties**."

BACKGROUND

A. COMPANY is engaged in the development and commercialization of certain pharmaceutical or cosmetic products;

B. DPT owns and has a broad spectrum of technologies for the development, formulation, testing, control, manufacture, filling and supply of pharmaceutical, over-the-counter and cosmetic products; and

C. COMPANY desires DPT to manufacture and supply Product (as hereinafter defined) to COMPANY, and DPT desires to do so.

NOW, THEREFORE, in consideration of the covenants, conditions and undertakings hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

AGREEMENT

ARTICLE 1
DEFINITIONS/INTERPRETATION

For the purposes of this Agreement, the following capitalized words and phrases shall have the following meanings**:**

1.1 "**Act**" means the US Federal Food, Drug and Cosmetic Act and Canada's Food and Drug Act and Regulations, as amended, and regulations promulgated thereunder.

1.2 "**Administrative Expenses**" means, in the context of any Product recall, the reasonable documented out-of-pocket expenses of notification or return of the recalled Product incurred by either of the Parties in any such corrective action.

1.3 "**Affiliate**" means, with respect to a Party, any corporation, limited liability company or other business entity controlling, controlled by or under common control with such Party, for so long as such relationship exists. For the purposes of this definition, control means:

(a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such corporation, limited liability company or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Law of the country of incorporation or domicile), as applicable.

1.4 "**New Drug Application**": "NDA" means a New Drug Application filed with the FDA as described in 21 C.F.R. § 314 (including any amendments and supplements thereto).

1.5 "**Annual Product Review**" A regular quality review of every licensed medicinal product as required per regulatory requirements. The purpose of this annual review is to verify the consistency of the existing process, the appropriateness of the current specifications, manufacturing, and control procedures, to highlight trends and identify product and process improvements, and to act where needed.

1.6 "**API**" means the active pharmaceutical ingredient identified on and having the chemical composition set forth in Schedule A attached hereto, that is contained in the Product(s), also referenced herein as the "Processing Material".

1.7 "**Applicable Law**" means all laws, ordinances, rules, rulings, directives and regulations of any Governmental Authority that apply to the development, manufacture, supply or commercialization of any Product or the other activities contemplated under this Agreement, including (i) all applicable federal, state and local laws, rules and regulations; (ii) the Act; (iii) regulations and guidelines of the FDA and other Regulatory Authorities, including cGMPs; and (iv) any applicable non-U.S. equivalents of any of the foregoing, including guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (as amended from time to time).

1.8 "**Bankruptcy Event**" means, with respect to a Party, (a) the making by it of a general assignment for the benefit of creditors, (b) the commencement by it of any voluntary petition in bankruptcy or suffering by it of the filing of an involuntary petition of its creditors, (c) the suffering by it of the appointment of a receiver to take possession of all, or substantially all, of its assets, (d) the suffering by it of the attachment or other judicial seizure of all, or substantially all, of its assets, (e) the admission by it in writing of its inability to pay its debts as they come due, or (f) the making by it of an offer of settlement, extension or composition to its creditors generally.

1.9 "**Business Day**" means any day other than a Saturday, a Sunday or any day on which commercial banks located in New York City, New York, U.S.A. are authorized or required to remain closed.

1.10 "**cGMPs**" means current good manufacturing practices and standards as set forth (and as amended from time to time) in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations, including 21 C.F.R. Sections 210 and 211, and any corresponding practices and standards under Applicable Law in the Territory, or the country in which the Product is manufactured hereunder, subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.

1.11 "**Change Control Request**" or "**CCR**" means the primary record in which the overall details of a change are captured and monitored.

1.12 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto performing similar functions.

1.13 "**Forecasted Needs**" means COMPANY's written estimate of the quantity of each Product that COMPANY anticipates ordering from DPT for each of the [***] ([***]) months following the month in which such estimate is provided. The [***] ([***]) months of Forecasted Needs is non-binding provided, however, the first [***] ([***]) months are firm and binding.

1.14 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any nation, state, country, city or other political subdivision, including any Regulatory Authority.

1.15 "**Label**", "**Labeled**", or "**Labeling**" means all labels and other written, printed, or graphic matter included or to be included upon: (i) the Product or any container or wrapper utilized with Product or (ii) any written material accompanying Product.

1.16 "**Launch Year**" means the period commencing on the first day following DPT's delivery of the initial invoice for Product to COMPANY and ending on December 31 of such calendar year.

1.17 "**Manufacturing Fee**" means the fee invoiced to COMPANY by DPT for services required of DPT to manufacture and package each Product. The Manufacturing Fee is quoted in single final Product unit increments (i.e., by the bottle or tube). The Manufacturing Fee shall include services for incoming inspection of materials, compounding of bulk Product, Packaging, testing Product for release, making Product ready for shipment, and one copy of the Certificate of Analysis. The Manufacturing Fee does not include, without limitation, any technical or development services support, Package engineering studies, validation studies or support, FDA audit support, extensive reporting requirements, or additional laboratory testing performed by an outside testing laboratory or testing beyond that required in the Specifications. These services are in addition to the Manufacturing Fee and shall be billed by the hour at DPT's then-prevailing Technical and Development Hourly Rate (as hereinafter defined) in accordance with Article 7 contained herein. In addition, the Manufacturing Fee does not include warehousing or distribution of Product, any materials costs or costs associated with establishing or manufacturing new materials such as art charges, die costs, plate costs, and packaging equipment change parts.

1.18 "**Safety Data Sheet**" or "**SDS**" means written or printed material concerning a hazardous chemical which is prepared in accordance with the regulations promulgated by the Occupational Safety & Health Administration, or any successor entity thereto.

1.19 "**Materials Fee**" is quoted in single final Product unit increments and is defined as DPT's Standard Cost (as hereinafter defined) plus a mark-up of ten percent (10%) for administration and carrying costs. Materials Fee does not include, without limitation, costs associated with establishing, testing or manufacturing components or new materials such as reference standards, reagents, art charges, die costs, molding or tooling costs, plate costs, and packaging equipment change parts.

1.20 "**Minimum Order Quantity**" means the smallest amount or number of a chemical, device, excipient, Labeling or Packaging component that a vendor will supply to DPT when it submits a purchase order to such vendor for such chemical, device, excipient, Labeling or Packaging component.

1.21 "**Package**" or "**Packaging**" means all primary containers, cartons, shipping cases, inserts or any other like material used in packaging, or accompanying, a Product.

1.22 "**Person**" means an individual, a corporation, a partnership, an association, a trust or other entity or organization, including a government or political subdivision or an agency thereof.

1.23 "**Product**" means each product set forth in a Project Protocol.

1.24 "**Project Protocol**" means a precise and detailed plan that is mutually agreed and executed by DPT and COMPANY which carefully describes the nature and scope of services to be rendered, Product to be delivered, and fees to be charged, including the relevant Specifications therefor. Project Protocols are generated for activities not included in the manufacturing and material fees.

1.25 "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity, including the FDA, with authority over the development, manufacture or commercialization of any Product(s) in any jurisdiction in any country where COMPANY may commercialize Product.

1.26 "**Specifications**" means the requirements and standards for each Product set forth on Schedule B, which may include (i) raw material specifications (including chemical, micro, and Labeling and Packaging specifications); (ii) sampling requirements (i.e., lab, chemical, and micro); (iii) compounding module, including compounding process and major equipment; (iv) intermediate specifications; (v) Packaging modules (including Packaging procedures, torque and fill weights); and (vi) finished Product specifications release criteria including DPT's Acceptable Quality Limits ("**AQLs**"). Specifications shall be established or amended from time to time upon the written agreement of both DPT and COMPANY via a Change Control Request in accordance with Article 6 below.

1.27 "**Standard Cost**" means, with respect to materials, the average actual cost to DPT of materials plus shipping and handling charges, incoming freight, scrap/yield loss adjustments and any other recurring costs directly attributable to acquiring such material(s).

1.28 "**Standard Operating Procedures**" or "**SOPs**" means DPT's detailed, written instructions to achieve uniformity of the performance of a specific process; the instructions usually cover more than one task or area covered by cGMP regulations.

1.29 "**Stock Keeping Unit**" or "**sku**" or "**SKU**" means a unique number assigned to a finished product.

1.30 "**Technical and Development Hourly Rate**" means the hourly rate charged by DPT technical and development personnel for services provided to customers of DPT at the time such services are provided.

1.31 "**Territory**" means those countries set forth in Schedule D.

1.32 "**Third Party**" means any Person other than DPT, COMPANY or their respective Affiliates.

1.33 "**Total Price**" means, for a unit of Product, the sum of the Manufacturing Fee and the Materials Fee.

1.34 "**DPT's Fault**" means and includes one or more of the following: (i) acts or omissions of DPT or its representatives (including those of its Affiliates designated to perform and/or carry out on its behalf activities under this Agreement) that amount to gross negligence or willful misconduct, (ii) failure of DPT or its representatives (including such Affiliates) to a) follow DPT's or such Affiliates' written procedures and standard operating procedures) ("DPT's Requirements") applicable to Processing and b) complete preventative maintenance activities pursuant to DPT's Requirements. For the avoidance of doubt, any Processing failure and/or damage or loss of API, Product or Processing Material, or any delay in making Product available to Company, arising out of a Processing Material Latent Defect shall not be DPT's Fault unless such Processing Material Latent Defect is attributable to aspects under DPT's control as stated in subsections (ii)(a) or (iii), above.

1.35 "**Disposition**" means either the release or rejection of a Batch, or part thereof, of Product by the quality unity of a Party pursuant to such Party's quality systems and, with respect to DPT, in compliance with the Quality Agreement. For purposes of this Agreement, any rejection by Company shall be in accordance with the provisions of the Quality Agreement.

1.36 "**Processing Material Latent Defect**" shall mean any defect in a Processing Material rendering the Processing Material nonconforming to the Processing Specifications, as applicable and with any other specifications agreed to for such Processing Material, or is otherwise defective, which defect is not reasonably discoverable through DPT's incoming goods inspection verification methods and procedures.

1.37 "**Expected Yield**" shall mean, for each Product after Processing of the first [***]Batches thereof, a number of units to be calculated as follows: the adjusted mean of the final yield minus three standard deviations; provided, however, after Validation and prior to completion of [***] Batches for the Product, the Expected Yield shall mean the number equal to the average of the number of units at [***]% of the theoretical yield of the Product. The adjusted mean of the final yield is the average Actual Yield for all previous Batches of the Product processed up to that point in time on a cumulative basis excluding any Batches agreed in writing by the Parties, through the process set forth below as having low yield due to identified production-related root causes not normally be expected during Processing. The Expected Yield for each presentation shall be recalculated after each subsequent [***] Batches of that Product.

1.38 Additional Definitions. Each of the following terms shall have the meaning described in the corresponding Section of this Agreement indicated below:

Term	Section
Agreement	Preamble
Anti-Corruption Laws	10.3.1
AQLs	1.26
COMPANY	Preamble
COMPANY Indemnitees	12.1.1
Confidential Information	11.1
Development Costs	8.1.2
Development Product	8.1.1
Disclosing Party	11.1
Dispute	14.1
DPT	Preamble
DPT Indemnitees	12.1.2
Effective Date	Preamble
Extended Term	13.1
Force Majeure	15.4
Indemnify	12.1.1
Initial Term	13.1
Laboratory	5.4.4
Liabilities	12.1.1
Party or Parties	Preamble
PPI	3.1.1
Prior CDA	11.1
Receiving Party	11.1
Recipients	11.2
Rejected Product	5.4.1
Term	13.1
Third-Party Claim	12.1.1
Trade Control Laws	10.4.1

1.39 Interpretations. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections, Schedules mean the particular Articles, Sections, Schedules to this Agreement and references to this Agreement include all Schedules hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (ii) the word “or” shall have its inclusive meaning of “and/or;” (iii) the word “notice” shall require notice in writing (whether or

not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (iv) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or similar words refer to this Agreement (including any Schedules); (v) provisions that require that a Party or the Parties “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing; (vi) words of any gender include the other gender; (vii) words using the singular or plural number also include the plural or singular number, respectively; (viii) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof; and (ix) provisions that refer to Persons acting “under the authority of DPT” shall include DPT’s Affiliates and those Persons acting “under the authority of COMPANY” shall include COMPANY’s Affiliates; conversely, those Persons acting “under the authority of DPT” shall exclude COMPANY and its Affiliates and those Persons acting “under the authority of COMPANY” shall exclude DPT and its Affiliates.

ARTICLE 2
MANUFACTURE AND SUPPLY

2.1 Manufacture and Purchase

. During the Term and subject to the terms and conditions of this Agreement, DPT agrees that it will manufacture and provide Product to COMPANY. COMPANY agrees to purchase from DPT, at least [***] ([***]) units from DPT. If COMPANY fails to purchase the Minimum Volume in any contract year, then within [***] ([***]) days after the end of such contract year, COMPANY shall pay DPT such dollar amount equal to the difference between the Minimum Volume less the actual number of units purchased by COMPANY from DPT for such contract year. DPT shall use commercially reasonable efforts to manufacture Product in accordance with the Specifications therefor, and in sufficient quantity to meet COMPANY’s Forecasted Needs.

For the avoidance of doubt, it is clarified that, during the Initial Term of this Agreement and any subsequent renewal periods, DPT may not conduct any formulation development, but may manufacture and supply products utilizing Roflumilast as an active pharmaceutical ingredient (including performing a site transfer for such products, if needed), either by itself or through its Affiliates, for and/or to Third Parties, if and only if, DPT does not utilize any of Company’s Roflumilast active pharmaceutical ingredient or Company’s associated intellectual property (if any), in the process of such manufacture and supply.

2.2 Commencement of Manufacturing for New Product

. No later than [***] ([***]) months prior to the estimated first delivery date of a new Product (or a new SKU of an existing Product), COMPANY agrees to notify DPT of its delivery requirements for such new Product (or new SKU of an existing Product) Forecast. COMPANY shall provide Forecasted Needs covering the [***] ([***]) month period commencing on the first day of the Launch Year in order to ensure timely delivery of Product. Firm orders shall be issued for the first [***] ([***]) months of the COMPANY’s Forecasted Needs with delivery dates based on the longest component lead time.

2.3 Supply of Materials

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2.3.1 Materials Supplied by COMPANY. Each Project Protocol shall set forth any material to be supplied by COMPANY to DPT for the manufacture and supply of Product thereunder. COMPANY shall, at COMPANY's cost and expense, provide DPT with such materials at a minimum of [***] ([***]) days prior to DPT's scheduled start of production of Product requiring said materials and in sufficient amounts for DPT's manufacture of Product but not to exceed quantities necessary to support [***] ([***]) months of the most recently supplied Forecasted Needs or the Minimum Order Quantity, whichever is greater. DPT will initiate required testing and release activities for Materials Supplied by the COMPANY, so as to not delay the planned start of any batch manufacturing per the agreed upon production schedule. COMPANY-supplied material in excess of these amounts shall be either subject to storage fees or returned to COMPANY at COMPANY's expense. All COMPANY-supplied material shall be shipped to DPT DDP (Incoterms 2020). In the event COMPANY ships or causes to ship such material freight collect, DPT shall invoice COMPANY for the cost of the freight plus a reasonable administrative fee which invoice shall be paid by COMPANY promptly upon receipt. DPT is hereby authorized by COMPANY to return to COMPANY, at COMPANY's cost and expense, any portion of COMPANY-supplied material for which no future production is planned. COMPANY shall be responsible for the quality of all COMPANY-supplied materials. COMPANY shall be responsible for the payment of all personal property and other taxes incident to the storage of COMPANY-supplied material at DPT. DPT warrants that, during the Term, it will maintain, for the benefit of COMPANY, complete and accurate records of the inventory of all such COMPANY-supplied materials. DPT will provide to COMPANY a monthly report of the ending monthly inventory balance of all COMPANY-supplied materials stored at DPT. This reporting will be supplied exclusively on DPT forms.

2.3.2 Title and Risk of Loss.

(a) Title to API supplied by or on behalf of Arcutis to DPT, and Product Processed therefrom, shall be and remain in Arcutis. DPT shall not grant, nor permit any creditor or other Third Party to acquire any security interest, lien, or other encumbrance in the API supplied by on behalf of Arcutis or the Product Processed by DPT.

(b) DPT's risk of loss or damage for Product Processed shall remain with DPT until collected by Arcutis or Arcutis' nominee at the Facility. Notwithstanding the foregoing, provided DPT makes Product available to Arcutis at the Facility on or before the Delivery Date, in the event that Arcutis does not remove from the Facility such Product on such Delivery Date, expect to the extent of DPT's Fault or failure to comply with storage and handling of the Product prior to such date, and always subject to the provisions of this Agreement, risk for loss and damage for such Product shall pass to Arcutis at 11:59 on such Delivery Date.

2.3.3 Materials Supplied by DPT. DPT shall be responsible for the supply, at the expense of COMPANY, of all other components necessary for the manufacture of Product. DPT will initiate required testing and release activities for Materials Supplied by the DPT so as not to delay the planned start of any batch manufacturing per the agreed production schedule. DPT will maintain released quantities of Materials Supplied by DPT in inventory to not delay the planned start of any batch manufacturing per the agreed production schedule. If the applicable Project Protocol requires that DPT utilize suppliers for raw materials and components that are not validated and approved DPT suppliers as of the Effective Date, then materials and components from such suppliers shall be treated as COMPANY-supplied materials. Unless supplier qualification services are part of the manufacturing services to be performed under a Project Protocol, DPT shall have no obligation to qualify new suppliers. All DPT-supplied materials will be billed to COMPANY on the respective invoice for Product, into which such DPT-supplied material was converted, as part of the Materials Fee.

2.3.4 Packaging and Labeling. COMPANY shall provide DPT with Specifications (including art proofs) for Packaging and Labeling of each Product, and DPT shall purchase, at the expense of COMPANY, such Packaging and Labeling in accordance with the Specifications. COMPANY assumes responsibility and liability for the content of all COMPANY-approved Labeling and Packaging and compliance with Applicable Laws.

2.3.5 Additional Charges. COMPANY shall be responsible for any additional charges (including, but not limited to, items such as brokerage fees, courier expenses, duty fees payable, etc.) that are incurred in the procurement of any materials, including Packaging and Labeling components, as detailed in the immediately preceding sub-sections 2.3.1, 2.3.2 and 2.3.3; required for the manufacture of each Product, irrespective of which Party to the Agreement is responsible for supplying such items.

2.4 Supply of Product.

2.4.1 Purchase of Product. COMPANY agrees to purchase from DPT all Product manufactured for COMPANY by DPT in accordance with COMPANY's purchase orders or Forecasted Needs in alignment with Section 2.1. Product shall be ordered by COMPANY by the issuance of separate, pre-numbered purchase orders in increments of full batches. Compounding batches may be split into a maximum of two (2) fill batches

2.4.2 Forecasted Needs. COMPANY shall provide DPT with its non-binding [***] ([***]) month projection with specific data as to its Forecasted Needs on or before August 31, 2021. Such Forecasted Needs shall be updated by COMPANY [***] on or before [***]on a rolling [***] ([***]) month basis. It is understood and agreed that with respect to all Forecasted Needs issued to DPT by COMPANY pursuant to the terms hereof, the forecast for the first [***] ([***]) months thereof shall constitute a firm order for Product, to the extent not the subject of a previous firm order, regardless of receipt of COMPANY's actual purchase order. COMPANY shall provide DPT with a confirmatory purchase order on or before the [***]day of [***]. DPT shall confirm receipt of a Forecast or purchase order within [***] business days of receipt. DPT may produce Product up to [***] ([***]) days prior to the requested delivery date in order to accommodate fluctuations in production demands. The remaining [***] ([***]) months of the Forecasted Needs shall be utilized by DPT for purposes of material acquisition on behalf of

COMPANY and DPT production planning. DPT shall attempt to minimize the material inventory purchased on behalf of COMPANY. Certain materials, however, may have long lead times or require a Minimum Order Quantity. Therefore, DPT must order and maintain the chemical and Packaging components necessary to support at least [***] ([***]) months of COMPANY's Forecasted Needs, or the applicable Minimum Order Quantity, whichever is greater. Should COMPANY subsequently reduce its Forecasted Needs, COMPANY will be financially responsible for any material purchased by DPT on COMPANY's behalf; provided that COMPANY is not permitted to reduce COMPANY's Forecasted Needs for any [***] ([***])-month period constituting a firm order. Any such material which is subsequently rendered in excess of that required to support up to [***] ([***]) months of COMPANY's Forecasted Needs may be subject to storage and inventory carrying fees. DPT may require a deposit for such materials.

2.5 Orders.

2.5.1 Time of Issuance. COMPANY shall issue written purchase orders for Product to DPT at least [***] ([***]) months prior to the requested delivery dates if the requirements are at or below [***] percent ([***]%) of the applicable Forecasted Needs. Each such written purchase order shall be subject to acceptance by DPT.

2.5.2 Contents of Purchase Orders. COMPANY's purchase orders shall designate the desired quantities of each Product, delivery dates and destinations, each in accordance with this Section 2.5. This Agreement allows for up to [***] ([***]) shipping destinations per batch of Product. Additional destinations can be accommodated for a shipping preparation fee to be negotiated by DPT and COMPANY.

2.5.3 Shipment. Shipment of Product shall be in accordance with COMPANY instructions, provided that such instructions comply with Applicable Law. Product will be shipped to COMPANY or its designee promptly following release, freight collect. At COMPANY's request, DPT may hold fully released Product in DPT's warehouse for a storage fee. Product held at DPT will be subject to payment in accordance with Section 3.2 as if such Product was shipped. If COMPANY requests DPT to make any miscellaneous small shipments of Product, material, or other items on COMPANY's behalf, COMPANY agrees to reimburse DPT for any shipping charges incurred by DPT.

2.5.4 Delivery Terms. All shipment of Product detailed in Schedule B hereof shall be EXW (Incoterms 2020) DPT's plant of manufacture. Title to, and risk of loss for, Product, shall transfer from DPT to COMPANY when DPT makes the Product available to COMPANY at DPT's plant of manufacture. COMPANY shall bear all risk of loss, delay, or damage in transit, as well as cost of freight and insurance.

2.6 Joint Steering Committee. A Joint Steering Committee shall be formed within 30 days of Effective Date. The Joint Steering Committee may meet quarterly to review performance. To the extent that there are any performance issues, escalation will be made to an Executive Steering Committee comprised of, at a minimum, respective Heads of Operations and Heads of Quality for both Parties.

2.7 No Conflicting Terms. The terms and conditions of this Agreement shall be controlling over any conflicting terms and conditions stated in the Project Protocol or Specifications (unless otherwise stipulated in writing referencing this Section 2.6). The Parties acknowledge that SOPs are considered to supplemental to master batch records, specification documents and standard methods of analysis. Specific instructions in master batch records, specification documents and standard methods of analysis will supersede instructions in SOPs (unless otherwise stipulated in the SOP document.

2.8 **Supply Failure**. Subject to the terms of this Agreement, and provided that such failure is not attributable to any inaction or action caused by COMPANY and accepting normal yield losses associated with the production of each Batch, in the event that DPT fails to deliver at least [***] ([***]%) of the quantity of Product set forth in any purchase order: (i) on or before the date that is [***] ([***]) days after the delivery date, COMPANY will issue letter of potential Supply Failure to DPT Site Head. In the event that supply issue is not rectified within [***] ([***]) days from initial delivery date, DPT shall be considered to be in "Supply Failure" status. Further, in the event of [***] [***] ([***]) day delivery delays in one calendar year, DPT shall be considered to be in "Supply Failure". Without limiting its obligations herein, DPT shall, within [***] ([***]) business days of becoming aware (if commercially feasible), inform COMPANY of any known or anticipated events or conditions that may result in such a Supply Failure.

2.9 **Consequences of and Remedies for a Supply Failure**. In the event of a Supply Failure, and without limiting any other remedy available to the COMPANY at law or equity: (i) DPT shall fulfill outstanding purchase order(s) with such quantities of Conforming Product as are immediately available; and (ii) unless and until such Supply Failure is remedied to COMPANY's satisfaction, COMPANY shall be entitled to source Product from an alternative manufacturing facility (that DPT shall provide non-financial technology transfer assistance to COMPANY in qualifying) and shall be relieved from its obligations under this Agreement to (x) purchase any quantities of Product subject to any outstanding purchase orders or forecasts and (y) submit any further purchase orders or forecasts.

ARTICLE 3
PRICING AND PAYMENT

3.1 Product Price

3.1.1 Manufacturing Fees. The initial Manufacturing Fees to be paid by COMPANY to DPT are set forth in Schedule C. DPT reserves the right to raise the prices set forth in any Project Protocol if change(s) to Applicable Law, including, but not limited to GMP or changes made under Article 6, increase the cost of manufacturing of the Product or of any other activities contemplated under this Agreement. In addition, the Parties hereto agree that increases to the Manufacturing Fees set forth in Schedule C shall be negotiated, in good faith, [***]. If the Parties are unable to agree on a re-negotiated price at least [***] ([***]) days prior to [***], then this Agreement, effective [***], shall continue in full force and effect with prices being adjusted to reflect the change in the most recently published monthly Producer Price Index for Pharmaceutical Preparation Manufacturing PCU 325412, issued by the Bureau of Labor Statistics, US Department of Labor ("**PPI**"), or comparable successor index, in July of the

preceding year as compared to the same month of the year prior thereto until such time as to when price negotiation can be completed.

(For example: If in July 2014 the PPI is 548.3 and then the previous year 2013 reflects a PPI of 530.5 the difference would be 17.8. The 17.8 would be divided by 530.5 resulting in a PPI increase of 3.4% in year 2015).

In addition, Manufacturing Fees are based on annual volumes for Product. DPT reserves the right to increase the Manufacturing Fees at the beginning of [***] ([***]) in the event that actual volumes are less than those volumes listed in Schedule C by more than [***] percent ([***]%).

Prices for new Product or new Product sizes, new batch sizes or Product configuration changes not initially included in Schedule C, shall be negotiated and DPT and COMPANY shall arrive at a mutual agreement with respect to prices at the time said new Product or new Product sizes are added to Schedule B.

Costs associated with establishing, testing or manufacturing components or new materials such as reference standards, reagents, art charges, die costs, molding or tooling costs, plate costs, and packing equipment change parts will be invoiced to COMPANY at DPT's cost on a net [***] ([***]) basis and COMPANY agrees to reimburse DPT for any such authorized expenditures made on COMPANY's behalf.

3.1.2 Materials Fees and Other Costs. The initial Materials Fees to be paid by COMPANY to DPT are listed in Schedule C. For the Launch Year, the Materials Fee will be listed in Schedule C within [***] ([***]) days of commencement of the initial commercial production of the applicable Product. After the Launch Year, the Materials Fee will be increased [***] and Schedule C shall be amended accordingly based on changes in DPT's Standard Cost for materials. In the event, however, the total underlying costs of Material Fee for a Product increases during any [***] by more than [***] percent ([***]%), DPT will provide documented cost justifications to COMPANY in connection with such cost change(s). Thereafter DPT may promptly upon the effective date of such increase of more than [***] percent ([***]%), increase its Materials Fee for said Product to COMPANY to compensate for the increase in such costs.

Material Fees for new Product or new Product sizes, new batch sizes or Product configuration changes not initially included in Schedule C, shall be established prior to the time of first production.

3.2 Payment

. Payment for all deliveries of Product and services shall be made in U.S. Dollars (USD), net [***] ([***]) days after the date of DPT's invoice therefor. Invoices shall be generated upon shipment of Product from DPT. Total invoice price shall be equal to the quantity of Product times the Total Price per unit of Product effective on the date of the Product release, as listed in Schedule B. Payments shall be made by check, wire transfer, electronic fund transfer or through other instrument accepted by DPT. Payments by wire or electronic fund transfer should be made to the following:

Account Name: DPT Laboratories, Ltd.
Account Number: [***]
Bank Name: The Private Bank
ABA Routing Number: (ACH/WIRE): [***]
SWIFT Code (US$) [***]
Bank Location: Chicago, IL USA
Contact: [***]

3.3 Late Payment. A late fee of [***] percent ([***]%) of total invoice can be added [***]. DPT, at its sole discretion, has the right to discontinue COMPANY's credit on future orders and to put a hold on any production or shipment of Product if COMPANY's account is not current. Such hold on production or shipment shall not constitute a breach of this Agreement by DPT. In the event credit is discontinued, a [***] percent ([***]%) material deposit paid by COMPANY to DPT will be required prior to DPT ordering any additional materials. In addition, a [***] percent ([***]%) Manufacturing Fee deposit will be required prior to DPT manufacturing any Product and the balance of the invoice for such Product must be paid in full prior to shipment.

3.4 Destruction Costs. DPT reserves the right to invoice COMPANY for all of the costs of destruction of any Product, unless such destruction relates to a Rejected Product arising from DPT's failure to comply with applicable written procedures.

3.5 Taxes. COMPANY shall bear all taxes, whether direct or indirect (including, by way of example, corporate income, sales and transfer taxes, and VAT), levies, and duties (including customs duties) as may be imposed on COMPANY (or for which COMPANY is required to act as withholding agent by any governmental body or authority on the subject matter of this Agreement), and COMPANY shall be responsible for the timely payment of such amounts to such governmental body or authority.

ARTICLE 4
PRODUCT TESTING

4.1 Certificates of Analysis. DPT shall test each lot of Product purchased pursuant to this Agreement before delivery to COMPANY. Each Certificate of Analysis shall set forth the items tested, specifications and test results for each lot delivered. DPT shall send one (1) Certificate of Analysis to COMPANY at the time of the release of Product. Extraordinary reporting or documentation, outside this Agreement, may be subject to an additional charge by DPT. Requests for raw data for specification testing of Product will not be considered extraordinary.

4.2 Stability Testing. DPT shall perform its standard stability test program as defined in DPT's SOPs or as separately agreed to in accordance with a Change Control Record for each Product contained herein. Stability requirements will be defined in a stability protocol with COMPANY APPROVAL. COMPANY shall receive a copy of the report generated in DPT's Annual Product Review for each Product in DPT's standard form as long as DPT is continuing to produce such Product for COMPANY and for as long as COMPANY's account is

current. If COMPANY elects to perform its own stability testing on Product, COMPANY agrees to provide DPT with a copy of the results from such testing on an annual basis.

4.3 Validation Studies or Additional Testing. It is understood and agreed by the Parties hereto that unless otherwise agreed, any validation studies costs shall be the sole responsibility of COMPANY. The Parties agree that for any validation studies or additional testing to be performed by DPT in connection with the Product, DPT and COMPANY shall enter into a specific written Project Protocol establishing methodology and pricing for such services.

4.4 Rejected Product

4.4.1 Rejection of Product by COMPANY. COMPANY shall have the right to reject any Product which fails to meet the Specifications or Applicable Law, in accordance with this Section 4.4 ("**Rejected Product**"). COMPANY shall, within [***] ([***]) days after its receipt of any shipment of Product and related Certificate of Analysis of Product batch (as described in Section 4.1 hereof), notify DPT in writing of COMPANY's rejection of the Product, specifying why the Product batch failed to meet the Specifications or Applicable Law, and any other claim relating to the Rejected Product batch accompanied with the supporting analyses or documentation. COMPANY's failure to provide such rejection notification within the [***] ([***]) day period specified above will be deemed for purposes of the Agreement to constitute COMPANY's acceptance of such Product batch. COMPANY shall grant to DPT the right to inspect, or test said Product batch. Inspection shall only be granted upon written approval by COMPANY. Additional testing or inspection of a lot being considered for rejection can only be tested under investigation with COMPANY approval. All necessary samples of Rejected Product shall be delivered to DPT and submitted for inspection and evaluation by DPT in accordance with DPT's SOPs to determine whether or not said Product meets the Specifications.

4.4.2 Replacement of Rejected Product. As to any Rejected Product agreed by the Parties as failing to meet the Specifications or determined by the Laboratory not to meet the Specifications, pursuant to Section 4.4.4 below (including in each case phases of or complete batches of bulk Product), DPT shall replace such Rejected Product (in an agreed upon batch order quantity, but in no event less than full batch increments) promptly after all requisite materials are available to DPT for the manufacture of replacement Product. If requested, DPT shall make arrangements with COMPANY for the return or disposal of Rejected Product.

4.4.3 Responsibility for Costs. For all of the validation batches of a Product produced by DPT, or in the event a Rejected Product fails to comply with the Specification due to COMPANY-supplied information, formulations or materials, or otherwise due to improper storage, transport or other mishandling by COMPANY, COMPANY shall bear [***]percent ([***]%) of all costs directly related to and invoiced for such validation or batch of Rejected Product including the cost of destruction of the Rejected Product, which shall be conducted and managed by DPT. Upon the completion of all necessary validation batches in the event a Rejected Product fails to comply with the Specification due to DPT's failure to comply with the applicable written procedures and such failure renders the Product unmarketable, DPT shall bear [***]percent ([***]%) of the Manufacturing Fees, costs of all materials used in manufacturing, including Company-supplied API, and costs of destruction. In the event Rejected Product fails to comply with the Specification, but such failure is not due to either COMPANY-supplied

information, formulations or materials or otherwise due to improper storage, transport or other mishandling by COMPANY, the COMPANY shall bear the cost of destruction and all Materials Fees and DPT shall bear the Manufacturing Fees related to such Rejected Product. Destruction of Rejected Product shall be in accordance with all Applicable Laws.

4.4.4 Resolution of Conflict. If DPT does not agree with COMPANY's determination that the Product fails to conform to the Specifications, then DPT shall so notify COMPANY within [***] ([***]) days of receipt of COMPANY's notice of non-conformity with respect to such Product and (if requested) Product sample. In the event of: (i) a conflict between the Parties with respect to the conclusions to be drawn from any test results or, (ii) a difference of opinion between the Parties regarding the rejection of any batch by DPT with respect to any shipment of Product in such batch, a sample of such Product batch shall be submitted by DPT to an independent testing organization, or to a consultant of recognized repute within the United States pharmaceutical industry, in either case mutually agreed upon by the Parties (such organization or consultant, the "**Laboratory**"), the appointment of which shall not be unreasonably withheld or delayed by either Party, for testing against the Specifications utilizing the methods set out in the Specifications. The determination of the Laboratory with respect to all or part of any shipment of Product shall be final and binding on the Parties. The fees and expenses of the Laboratory testing shall be borne entirely by the Party against whom such Laboratory's findings are made. If results from the Laboratory are inconclusive, final resolution will be settled in accordance with Article 13 below.

4.4.5 Product Recall. Each of DPT and COMPANY will immediately inform the other in writing if it believes one or more lots of any Product(s) should be subject to recall from distribution, withdrawal or some other field action. In the event it is determined that such a recall resulted from a breach by either Party of any of its representations, warranties, duties or obligations under the Agreement, such Party shall be responsible for the costs of the recall and shall reimburse the other Party as necessary; provided that if both Parties share responsibility with respect to such recall, the costs shall be shared in the ratio of the Parties' contributory responsibility. COMPANY shall, with respect to any recall of any Product, abide by all Healthcare Distribution Management Association published guidelines for product recall reimbursement in effect at the time of the recall. In the event that any such recall results solely from the breach of DPT's warranties under this Agreement, DPT shall be responsible for the Administrative Expenses of such recall, in any case not to exceed [***] U.S. dollars ($[***] USD) per Product recall incident, as well as for the cost of replacing the recalled Product.

ARTICLE 5
REGULATORY AND QUALITY RESPONSIBILITIES

5.1 Materials Testing. For each lot of materials supplied by COMPANY, DPT shall perform the quality control and inspection tests as set forth in the Specifications unless COMPANY has made arrangements in writing to supply pre-approved material. All materials and Packaging supplies shall, when received by DPT, be submitted for analysis and evaluation in accordance with DPT's SOPs to determine whether or not said materials or Packaging supplies meet the Specifications. DPT shall have the right to reject any pre-approved material which does not conform with the Specifications. The cost of all such analyses and evaluations shall be borne

by DPT except as otherwise provided in Section 2.3 of this Agreement**.** DPT agrees to maintain and, if necessary, make available records of all such analyses and evaluations.

5.2 Safety Data Sheets. Prior to DPT's receipt and testing of any materials components or finished Product, and as a condition precedent of any testing or formulation work by DPT pursuant to this Agreement, COMPANY shall provide DPT with Certificates of Analysis and SDS for any materials supplied by COMPANY, as well as any finished Product and any components to be supplied by COMPANY which are necessary for the manufacture of each Product. Any materials, components or Product requiring disposal shall be presumed hazardous unless otherwise provided in the SDS information provided.

5.3 Regulatory Inspection. DPT shall notify COMPANY, in accordance with the Quality Agreement , if an authorized agent of the FDA, EMA or other Regulatory Authority or Governmental Authority visits DPT's manufacturing facility and requests or requires information or changes which specifically pertain to COMPANY Product. Any time spent on Regulatory Authority or Governmental Authority visits or requests specific to COMPANY Products will be billed to COMPANY by DPT at DPT's standard hourly rates.

5.4 Regulatory Communications & Filings. COMPANY agrees to provide DPT with copies of any sections of NDA's, or other regulatory filings and Regulatory Authority correspondence applicable to each Product manufactured or tested by DPT, and copies of any changes in or updates to the same as they, from time to time, hereafter occur.

5.5 Access to DPT's Facilities. During the Term, COMPANY shall have access to DPT's facilities at a mutually agreeable time for the sole purpose of auditing DPT's compliance with cGMP and the Act in the manufacture of Products hereunder. Such access shall in no way give COMPANY the right to any of DPT's confidential or proprietary information. Furthermore, such audits shall normally be limited in frequency to [***] every [***] ([***]) months for [***] ([***]) days and limited to a maximum number of [***] ([***]) employees of COMPANY who are subject to written obligations of confidentiality and non-use at least as protective of DPT and DPT's Confidential Information as the terms of this Agreement. COMPANY has the right to conduct additional audits on a "for cause" basis. COMPANY shall be permitted to have one of its employees or consultants on site for the purpose of observing, reporting on and consulting as to the performance of the services associated with manufacture of Products hereunder. Timing of such site visits shall be mutually agreed upon by COMPANY and DPT. Such employee or consultant shall be subject to and agree to abide by confidentiality obligations and DPT's standard operating procedures for visitors.

ARTICLE 6
CHANGES TO PROCESS OR PRODUCT

6.1 Changes by COMPANY. If COMPANY at any time requests a change to any Product and DPT agrees such change is reasonable with regard to Product manufacture; (i) such change shall be incorporated within the Master Batch Record or Specifications via a written CCR

reviewed and agreed upon in writing by both DPT and COMPANY; (ii) the Parties shall adjust the Total Price of Product, if necessary, and Schedule B shall be amended accordingly; and (iii) COMPANY shall pay DPT for the costs associated with such change including, but not limited to, any additional development or validation studies required, charged at DPT's then-prevailing R&D rates.

6.2 Changes by DPT. DPT agrees that any changes to the Product developed by DPT, which may be incorporated into the Product shall require the written approval of COMPANY via a CCR prior to such incorporation. At the time of such incorporation, such changes shall become part of the Specifications. It is also agreed that any filings with any Regulatory Authority necessitated by any such change shall be the sole responsibility of COMPANY.

6.3 Changes or Fees by Regulatory Authorities. The Parties agree that any changes required by a Regulatory Authority, shall be incorporated into the Product as evidenced by the written approval of COMPANY via a CCR prior to such incorporation. Any actual or potential additional Product costs, fees or expenses, including but not limited to items such as regulatory user fees, serialization fees or similar such items shall be the sole responsibility of COMPANY. At the time of such incorporation, such changes shall become part of the Specifications. If DPT is required by Regulatory Authority to perform validation studies for purposes of validating new manufacturing process or cleaning procedures or new material and finished Product assay procedures with respect to Product in order to continue to engage in the manufacture of said Product for COMPANY, such studies shall be agreed to by the Parties and set forth in a new Project Protocol. In the event the Parties are unable to reach agreement with respect to such Project Protocol, then DPT shall be under no obligation to perform such studies or otherwise continue the manufacture of the Product affected by said regulation. Any costs to DPT resulting from the operation of this Section 6.3 shall be reimbursed by COMPANY by way of adjustments to the Manufacturing Fee, Materials Fee or via an annual charge.

6.4 Obsolete Inventory. Any COMPANY-specific inventory relating to a Product or Development Product (as defined below), including, but not limited to, materials, expired materials, work-in-process, bulk Development Product, waste by-products, testing supplies, stability samples, work-in-process, and any Product or finished good rendered obsolete as a result of formula, artwork, Minimum Order Quantities, or Labeling or Packaging changes requested by COMPANY or by changes required by a Regulatory Authority, or at the conclusion, revision or termination of the development project shall be reimbursed to DPT by COMPANY at DPT's Materials Fee and unless otherwise instructed by COMPANY and agreed to by DPT, will be shipped to COMPANY for destruction by COMPANY. COMPANY shall bear [***] percent ([***]%) of all shipping and destruction costs related to said obsolete inventory. COMPANY shall destroy any such inventory in accordance with all Applicable Laws and COMPANY shall Indemnify (as hereinafter defined) DPT for any liability, costs or expenses, including attorney's fees and court costs, relating to COMPANY's failure to dispose of such inventory in accordance with such laws and regulations. COMPANY shall also provide DPT with all manifests and other applicable evidence of proper destruction as may be requested by DPT or required by applicable law. DPT shall provide written notification to COMPANY of its intent to dispose of or store obsolete inventory. If DPT does not receive disposition instructions from COMPANY within [***] ([***]) days from date of notification, obsolete

inventory remaining at DPT's facilities shall be subject to a deposit covering the standard cost of the obsolete inventory and storage and or destruction fees at DPT's discretion.

ARTICLE 7
TECHNICAL & DEVELOPMENT SERVICES

7.1 Technical & Development Services

7.1.1 Development Product. From time to time, COMPANY may request, in writing, that DPT evaluate, develop, manufacture, test or provide price quotations for certain new items which may become Product (hereinafter referred to as "**Development Product**") on behalf of COMPANY. If DPT agrees to perform such services, DPT shall so notify COMPANY within [***] ([***]) days of its receipt of COMPANY's. To the extent that DPT agrees to perform any services hereunder for COMPANY, DPT shall only be obligated to act in good faith and to use reasonable efforts to accomplish the desired results as outlined in the relevant Project Protocol. Nothing herein shall obligate DPT to achieve any specific results and DPT makes no warranties or representations that it will be able to achieve the desired results.

7.1.2 Project Protocol. Should DPT agree to perform any services hereunder, DPT shall submit a written development proposal in the form of a Project Protocol to COMPANY identifying DPT's best estimate of the cost of such services (the "**Development Costs**"). This estimate shall include, but not be limited to, labor hours for development, testing, scale up, stability, report writing, etc., as well as all reasonably foreseeable associated tasks and expenses. If this estimate is acceptable to COMPANY and COMPANY so notifies DPT by approving the Project Protocol in writing, DPT shall begin work as outlined in the Project Protocol. It is understood between both Parties that during any development project unforeseen circumstances may evolve, including, but not limited to, termination of any further activity due to unacceptable results, significant reevaluation due to marginal results. DPT will promptly notify COMPANY of any such unforeseen circumstances before proceeding at which time either COMPANY or DPT may terminate the project or mutually agree to amend or completely revise the Project Protocol. In the case where the project is terminated or revised, COMPANY will be obligated to pay for all of the work performed by DPT up to that point plus any noncancellable expenses incurred by DPT in connection with the relevant Project Protocol.

7.1.3 Costs. Material costs involved will be billed to COMPANY at DPT's cost plus mark-up of [***] ([***]%) for administration and carrying costs. The Development Costs shall be paid to DPT in accordance with DPT's standard invoicing procedures regardless of whether DPT is able to accomplish the results which COMPANY requested. All invoices shall be paid by COMPANY in accordance with Article 3 above.

7.2 Commercial Production of Development Project. In addition to the foregoing, in the event DPT develops a new Development Product for COMPANY and COMPANY elects to market, sale, license, or transfer such Product, such Product may be added to this Agreement and Schedule B shall be amended accordingly. At or near the beginning of any development project, DPT agrees to send to COMPANY a written proposal which will provide a good faith estimate of Manufacturing Fees and Materials Fees along with related assumptions. The price which COMPANY (or any such Third Party) shall pay to DPT for such Product shall be based

upon the Manufacturing Fee and Material Fee estimate provided in good faith by DPT under this Section 7.2 subject to revision for final packaging configuration and final cost and Manufacturing Fee and Material Fee adjustment pursuant to Article 3. Once COMPANY completes the development of a finished product prototype (which shall include final primary container selection filled with Development Product), DPT will provide an updated estimate of the Manufacturing Fee. DPT may also provide an updated estimate of the Materials Fee, should specifications be known for these items at such time.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 No Licenses. COMPANY neither transfers nor licenses DPT by operation of this Agreement under any of its patent rights, copyrights or other proprietary rights, except as specifically set forth in this Agreement.

8.2 Ownership of Inventions. All DPT Intellectual Property shall remain the sole and exclusive property of DPT. "DPT Intellectual Property" means any Technology (defined below) consisting of DPT manufacturing or laboratory testing processes, procedures, information or methods (whether or not created, developed or produced pursuant to the Agreement) to the extent (i) such Technology is generally applicable to DPT's business and is not related solely to COMPANY's Product and (ii) the practice of such Technology does not require any use of COMPANY Confidential Information. "Technology" means any (i) invention (whether or not patentable), ideas, know-how, works of authorship, modifications, technology, materials, software, formulations, techniques, developments, ideas, concepts, discoveries, designs, algorithms, models, formulations, improvements, protocols, data and proprietary information; and (ii) patents, copyrights, trademarks, service marks, trade secrets, or other intellectual property rights in and/or to the foregoing. Except for DPT Intellectual Property, all Technology developed or generated pursuant to this Agreement in the course of performing services required of DPT to manufacture and Package each Product or through the use of any information or materials provided by COMPANY hereunder, including without limitation new formulations, uses, processes or compositions, and all intellectual property rights in and to the foregoing, (collectively, "Project IP") shall be the exclusive property of COMPANY and DPT hereby assigns all right, title and interest in and to the foregoing to COMPANY. DPT agrees to assist COMPANY in securing for COMPANY any patents, copyrights or other proprietary rights in such Project IP, and to perform all acts that may be reasonably required to vest in COMPANY all right, title and interest in such Project IP and DPT shall be compensated at its standard rates for such time of DPT employees spent and reimbursed for its reasonable out-of-pocket expenses to provide such assistance requested by COMPANY. All costs and expenses associated with establishing COMPANY's rights therein shall be COMPANY's responsibility, and additionally, if such activities exceed what is customary and reasonable for such activities, DPT may require fees equal to its standard rates for such time of DPT employees spent and reimbursement for its reasonable out-of-pocket expenses for such activities requested by COMPANY.

8.3 Licenses to COMPANY. DPT agrees that if, in the course of performing the services required of DPT to manufacture and Package each Product, DPT incorporates into any Project IP or Product or utilizes in the performance of the services required of DPT to manufacture and Package each Product any pre-existing invention, discovery, original works of

authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by DPT or in which DPT has an interest ("Prior Inventions"), DPT hereby grants COMPANY a non-exclusive, royalty-free, perpetual, transferable, worldwide license (with the right to grant and authorize sublicenses) under such Prior Inventions to make, have made, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit the Project IP and Product. DPT will not knowingly incorporate any invention, improvement, development, concept, discovery, work of authorship or other proprietary information owned by any third party into any Project IP or Product without COMPANY's prior written permission.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1 DPT Warranties and Representations. DPT represents and warrants the following:

9.1.1 DPT is a limited partnership duly organized, validly existing and in good standing under the laws of the State of Texas.

9.1.2 DPT has all requisite power and authority to enter into this Agreement. The Person signing this Agreement has the necessary corporate authority to legally bind DPT to the terms set forth herein.

9.1.3 DPT's execution of this Agreement and performance of the terms set forth herein will not cause DPT to be in conflict with or constitute a breach of its organizational documents nor any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound.

9.1.4 This Agreement is a legal, valid and binding obligation, enforceable against DPT in accordance with the terms and conditions hereof, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by the principles governing the availability of equitable remedies.

9.1.5 DPT will provide COMPANY with prompt written notice if any of the representations and warranties in this Section 9.1 become untrue.

9.2 COMPANY Warranties and Representations. COMPANY represents and warrants the following:

9.2.1 COMPANY is a corporation duly organized, validly existing and in good standing under the laws of Delaware.

9.2.2 COMPANY has all requisite power and authority to enter into this Agreement. The Person signing this Agreement has the necessary corporate authority to legally bind COMPANY to the terms set forth herein.

9.2.3 COMPANY's execution of this Agreement and performance of the terms set forth herein will not cause COMPANY to be in conflict with or constitute a breach of its organizational documents nor any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound.

9.2.4 To COMPANY's knowledge and belief, there are no suits, actions, claims, proceedings, or investigations pending or threatened by or before any court, by any Person relating to Product and matters set forth herein.

9.2.5 COMPANY's execution of this Agreement and performance hereunder are in, and will be in, compliance with any Applicable Law in all material respects.

9.2.6 This Agreement is a legal, valid and binding obligation, enforceable against COMPANY in accordance with the terms and conditions hereof, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by the principles governing the availability of equitable remedies.

9.2.7 COMPANY shall bear sole responsibility for all material supplied by COMPANY to DPT, including the pre-approved material and the validity of all test methods and appropriateness of all Specifications. In addition, COMPANY shall bear sole responsibility for all regulatory approvals, filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies. COMPANY further warrants that it has obtained any and all necessary approvals from all applicable Regulatory Authorities necessary to manufacture and distribute all Product under this Agreement.

9.2.8 As of the Effective Date, there are no claims, judgments or settlements against or owed by COMPANY or its Affiliates, or pending or threatened claims or litigation, relating to API, Products, Packaging and Labeling or any Company-supplied materials.

9.2.9 COMPANY will provide DPT with prompt written notice if any of the representations and warranties in this Section 9.2 become untrue.

9.3 Anti-Corruption.

9.3.1 Each Party understands that the other is required to and does abide by the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act and any other applicable anti-corruption laws (collectively, the "**Anti-Corruption Laws**"). Each Party represents and warrants to the other that no one acting on its behalf will give, offer, agree or promise to give, or authorize the giving directly or indirectly, of any money or thing of value to anyone as an inducement or reward or favorable action or forbearance from action or the exercise of influence (a) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (b) to any political party, official of a political party, or candidate, (c) to an intermediary for payment to any of the foregoing, or (d) to any other Person in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license.

9.3.2 COMPANY understands that DPT may immediately suspend its manufacture and supply of Product, in its sole discretion and without notice, if the actions or inactions of COMPANY become subject to an investigation of potential violations of the Anti-Corruption Laws. Moreover, each Party understands and agrees that if a party determines that the other party failed to comply with the provisions of any Applicable Law, including the Anti-Corruption Laws, such party may immediately terminate this Agreement, and any of its manufacture and supply obligations hereunder, in its sole discretion and without notice.

9.3.3 Each Party warrants that all Persons acting on its behalf will comply with all Applicable Laws in connection with all work under this Agreement, including the Anti-Corruption Laws if any, prevailing in the country(ies) in which such Party has its principal places of business.

9.3.4 Each Party further warrants and represents that should it learn or have reason to suspect any breach of any representation or warranty in this Section 9.3 it will immediately notify the other Party.

9.3.5 Each Party may appoint a certified public accounting firm to perform a financial audit to determine whether the other Party is in compliance with the terms of this Section 9.3. Each Party hereby agrees to grant the certified public accounting firm commercially reasonable access to its books, records, systems and accounts to the extent they pertain to transactions covered by this Agreement and are necessary for such purpose.

9.4 Trade Control Laws.

9.4.1 Each Party will fully comply with all applicable export control, economic sanctions laws and anti-boycott regulations of the United States of America and other governments, including the U.S. Export Administration Regulations (Title 15 of the U.S. Code of Federal Regulations Part 730 et seq.) and the economic sanctions rules and regulations implemented under statutory authority or President's Executive Orders and administered by the U.S. Treasury Department's Office of Foreign Assets Control (Title 31 of the U.S. Code of Federal Regulations Part 500 et seq.) (collectively, "**Trade Control Laws**").

9.4.2 Each Party acknowledges and confirms that Trade Control Laws apply to its activities, its employees and Affiliates under this Agreement.

9.4.3 COMPANY acknowledges that it shall be solely and exclusively responsible for the preparation of all import and export documentation and compliance with all applicable Trade Control Laws, except as otherwise agreed by the Parties in writing. COMPANY represents and warrants that is shall not take any unilateral action to identify or otherwise name DPT as the importer or exporter of record for any of the aforementioned items.

9.4.4 No Product will be directly or indirectly shipped by the other Party to any country subject to U.S. or U.N. economic sanctions without the necessary licenses.

9.4.5 DPT shall not be required by the terms of this Agreement to be directly or indirectly involved in the provision of goods, services or technical data that may be prohibited by applicable Trade Control Laws if performed by DPT. It shall be in the sole discretion of DPT to

refrain from being directly or indirectly involved in the provision of goods, services or technical data that may be prohibited by applicable Trade Control Laws.

9.4.6 Each Party hereby represents and warrants that it is not included on any of the restricted party lists maintained by the U.S. Government, including the Specially Designated Nationals List administered by the U.S. Treasury Department's Office of Foreign Assets Control; the Denied Persons List, Unverified List or Entity List maintained by the U.S. Commerce Department's Bureau of Industry and Security; or the List of Statutorily Debarred Parties maintained by the U.S. State Department's Directorate of Defense Trade Controls.

9.4.7 Each Party shall commit to maintaining awareness of the importance of Trade Control Laws throughout its organization. Each Party shall take such actions as are necessary and reasonable to prevent Product from being exported or re-exported to any country, entity or individual subject to U.S. trade sanctions, unless prior approval of the other Party, and relevant permission or license from the U.S. government has been obtained.

9.4.8 Each Party will keep accurate and consistent records of all transactions under this Agreement covered by the Trade Control Laws for a minimum of five (5) years from the date of export or re-export; the date of expiration of any applicable license; or, other approval or reliance on any application of license exception or exemption.

9.4.9 COMPANY shall be the importer or exporter of record for all such import or export activities. COMPANY shall cooperate with DPT as reasonably necessary to permit DPT to comply with the laws and regulations of the United States, including Trade Control Laws and Anti-Corruption Laws, and the laws and regulations other country relating to the control of import or export of Product, Active Pharmaceutical Ingredient, chemical, Labeling or Packaging components (or related technical information or data).

9.5 DPT Product Warranties. DPT represents and warrants that:

9.5.1 All Product delivered by DPT shall have been manufactured by DPT in compliance with applicable FDA regulations and current Good Manufacturing Practices as that term is defined under the Act.

9.5.2 All Product sold pursuant to this Agreement by DPT during the Term, at the time of pick-up by COMPANY, will have been manufactured in accordance with the Specifications for the release of the Product or pursuant to exceptions approved by COMPANY at the time of manufacture.

9.6 COMPANY Product Warranties. COMPANY represents and warrants that:

9.6.1 All Labeling, copy and artwork approved, designated or supplied by COMPANY shall be in compliance with all Applicable Laws. Compliance with all Applicable Laws concerning Packaging and Labeling shall be the sole responsibility of COMPANY, provided that DPT purchases such Packaging and Labeling as provided in Section 2.3.3.

9.6.2 No COMPANY designated formulas, components or artwork related to the Product violate or infringe any patent, copyright or trademark laws.

9.6.3 COMPANY has or will have the approval of the FDA to manufacture, sell and distribute the Product into the consumer marketplace and COMPANY assumes any and all responsibility for the manufacture, sale and distribution of the Product in the event that such approval was never provided by the FDA, or was initially provided but subsequently withdrawn by the FDA.

9.6.4 The manufacture, sale, offer for sale, use, import and commercialization of Product will not infringe or misappropriate the patent or other proprietary rights of any Third Parties.

9.7 Disclaimer. EACH PARTY AGREES AND ACKNOWLEDGES THAT, EXCEPT AS SET FORTH IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, IMPLIED OR STATUTORY, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST NON-INFRINGEMENT OR THE LIKE, OR ARISING FROM COURSE OF PERFORMANCE.

9.8 Change of Control.

9.8.1 This Agreement may not be transferred or assigned, in whole or in part, by either Party without prior written permission of the other Party. Notwithstanding, either Party may assign or transfer this Agreement, in whole or in part, to any of its current Affiliates notifying such fact to the other Party in writing.

Any permitted assignee shall assume all obligations and shall be entitled to all rights of the assigner under this Agreement. It is understood and agreed between the Parties that the Party who assigns this Agreement or any right or obligation hereunder shall (as long as it remains a surviving entity) be responsible on a joint and several basis of the fulfillment by the assignee of the provisions of this Agreement.

9.8.2 Either Party may assign this Agreement, upon written notice to the other Party, to any entity acquiring all or substantially all of its business to which this Agreement relates.

ARTICLE 10
CONFIDENTIALITY

10.1 Definition. "**Confidential Information**" means the terms and provisions of this Agreement (each of which shall be the Confidential Information of both Parties) and all other information and data, including all notes, books, papers, diagrams, documents, reports, e-mail, memoranda, visual observations, oral communications and all other data or information in whatever form, that one Party or any of its Affiliates or representatives (the "**Disclosing Party**") has supplied or otherwise made available to the other Party or its Affiliates or representatives (the "**Receiving Party**") hereunder, including those made prior to the Effective Date of this Agreement. This Article 10 shall supersede that certain confidentiality agreement between the

Parties dated August 4, 2017 (the "**Prior CDA**"), and all Confidential Information disclosed pursuant to the Prior CDA shall be deemed to have been disclosed hereunder.

10.2 Obligations. The Receiving Party shall protect all Confidential Information of the Disclosing Party against unauthorized use and disclosure to Third Parties with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The Receiving Party shall be permitted to use the Confidential Information of the Disclosing Party solely as reasonably necessary to exercise its rights and fulfill its obligations under this Agreement. The Receiving Party shall not disclose the Confidential Information of the Disclosing Party to any Third Party other than to its Affiliates, and its and their respective directors, officers, employees, subcontractors, sublicensees, consultants, and attorneys, accountants, banks and investors (collectively, "**Recipients**") who have a need to know such information for purposes related to this Agreement and who are made aware of the confidentiality obligations set forth in this Agreement or are bound by obligations of confidentiality at least as protective of such Confidential Information as those set forth in this Agreement. The Receiving Party shall be responsible for any disclosures made by its Recipients in violation of this Agreement.

10.3 Exceptions

10.3.1 Restriction Limitations. The restrictions related to use and disclosure under this Article 10 shall not apply to any information to the extent the Receiving Party can demonstrate by competent evidence that such information:

(1) is (at the time of disclosure by the Disclosing Party) or becomes (after the time of such disclosure by the Disclosing Party) known to the public or part of the public domain through no breach of this Agreement by the Receiving Party, or any Recipient to whom the Receiving Party disclosed such information, of its confidentiality obligations to the Receiving Party; or

(2) was known to, or otherwise in the possession of, the Receiving Party prior to the time of disclosure by the Disclosing Party;

(3) is disclosed to the Receiving Party on a non-confidential basis by a Third Party who is not, to the actual knowledge of the Receiving Party, prohibited from disclosing it without breaching any confidentiality obligation to the Disclosing Party; or

(4) is independently developed by or on behalf of the Receiving Party or any of its Affiliates, as evidenced by its written records, without use of or access to the Confidential Information.

10.3.2 Disclosure Required by Law. The restrictions set forth in this Article 10 shall not apply to the extent that the Receiving Party is required to disclose any Confidential Information under law or by an order of a Governmental Authority; provided that the Receiving Party: (a) provides the Disclosing Party with prompt written notice of such disclosure requirement if legally permitted, (b) affords the Disclosing Party an opportunity, and cooperates with the Disclosing Party's efforts, to oppose or limit, or secure confidential treatment for such required disclosure (at the Disclosing Party's expense), and (c) if the Disclosing Party is

unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the Receiving Party is legally required to disclose as advised by the Receiving Party's legal counsel.

10.4 Nondisclosure of Terms. Each Party agrees not to issue any press releases, reports, or other statements in connection with this Agreement intended for use in the public or private media or otherwise disclose the terms of this Agreement to any Third Party without the prior written consent of the other Party hereto, which consent shall not be unreasonably withheld, except to such Party's attorneys, advisors and others on a need to know basis in each case consistent with customary practice under circumstances that protect the confidentiality thereof. Notwithstanding the foregoing, each Party may make announcements concerning the subject matter of this Agreement if required by Applicable Law or any securities exchange or Governmental Authority or any tax authority to which any Party is subject or submits, in which case the Party making such announcement shall provide the other Party with a copy of such announcement at least [***] ([***]) Business Days prior to issuance, to the extent practicable under the circumstances, and shall only disclose information required by Applicable Law or such exchange or authority. Additionally, and notwithstanding anything to the contrary contained herein, COMPANY may disclose this Agreement as required by and/or in order to comply with the requirements of the United States Securities and Exchange Commission or any other agency governing publicly traded companies, including in connection with COMPANY's public filings.

10.5 Right to Injunctive Relief. Each Party agrees that breaches of this Article 10 may cause irreparable harm to the other Party and shall entitle such other Party, in addition to any other remedies available to it (subject to the terms of this Agreement), to the right to seek injunctive relief enjoining such action.

10.6 Ongoing Obligation for Confidentiality. The Parties' obligations of confidentiality, non-use and non-disclosure under this Article 10 shall survive any expiration or termination of this Agreement for [***] ([***]) years.

10.7 DPT Business Model. COMPANY acknowledges that as a contract manufacturing organization, DPT's business involves the application of its expertise, technology and know-how to numerous pharmaceutical and other products and that DPT retains the right (subject to its obligations under the applicable confidentiality provision or agreement) to apply such expertise, technology and know-how to a variety of products or services.

ARTICLE 11
INDEMNIFICATION AND INSURANCE

11.1 Indemnification.

11.1.1 Indemnification by DPT. DPT hereby agrees, at its sole cost and expense, to defend, hold harmless and indemnify, to the extent permitted by Applicable Law, (collectively, "**Indemnify**") COMPANY and its Affiliates and their respective directors, officers and employees of such Persons and the respective successors and assigns of any of the foregoing (the "**COMPANY Indemnitees**") from and against any and all liabilities, damages, penalties, fines, costs and expenses (including, reasonable attorneys' fees and other expenses of litigation) (collectively, "**Liabilities**") resulting from suits, claims, actions and demands, in each case

brought by a Third Party (each, a "**Third-Party Claim**") against any COMPANY Indemnitee and arising from or occurring as a result of: (a) any material breach of any of DPT's obligations, representations, warranties or covenants under this Agreement; or (b) the negligence or willful misconduct of a DPT Indemnitee. DPT's obligations to Indemnify COMPANY Indemnitees pursuant to this Section 11.1.1 shall not apply to the extent any such Liabilities are the result of a material breach by COMPANY of its obligations, representations, warranties or covenants under this Agreement or any COMPANY Indemnitee's gross negligence or willful misconduct. Notwithstanding the foregoing, under no circumstances shall DPT have any responsibility for product liability or personal injury claims of such third parties which arise from the sale, marketing, promotion, distribution or any use of Product which meets the Specifications.

11.1.2 Indemnification by COMPANY. COMPANY hereby agrees to Indemnify DPT and its agents, directors, officers and employees and the respective successors and assigns of any of the foregoing (the "**DPT Indemnitees**") from and against any and all Liabilities resulting from Third-Party Claims against any DPT Indemnitee arising from or occurring as a result of: COMPANY's negligence, willful misconduct or any breach of COMPANY's obligations, representations, warranties or covenants provided for herein or which arise out of the marketing promotion, distribution, use, testing or sales of any Product, including, without limitation, any Third Party Claim, express, implied or statutory, made as to the efficacy, safety, or use to be made of Product, and Third Party Claims made by reason of any Product Labeling or any Packaging containing Product. COMPANY's obligations to Indemnify DPT Indemnitees pursuant to this Section 11.1.2 shall not apply to the extent any such Liabilities are the result of a material breach by DPT of its obligations, representations, warranties or covenants under this Agreement or any DPT Indemnitee's negligence or willful misconduct.

11.1.3 Procedure. To be eligible to be Indemnified hereunder, the indemnified Person shall provide the indemnifying Party with prompt written notice of the Third-Party Claim giving rise to the indemnification obligation pursuant to this Section 11.1.3 and the right to control the defense (with the reasonable cooperation of the indemnified Person) or settlement any such claim; provided, however, that the indemnifying Party shall not enter into any settlement that admits fault, wrongdoing or damages without the indemnified Person's written consent, such consent not to be unreasonably withheld or delayed. The indemnified Person shall have the right to join, but not to control, at its own expense and with counsel of its choice, the defense of any claim or suit that has been assumed by the indemnifying Party.

11.2 Product Liability Insurance. Each Party shall, during the Term and for [***] ([***]) years after termination or expiration of this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company (provided however that DPT may satisfy all or part of its obligation through its insurance captive or self-insurance) product liability insurance providing protection against any and all claims, demands, and causes of action arising out of any defects, alleged or otherwise, of the Product(s) or their use, design or manufacture, or any material incorporated in the Product(s). The amount of coverage shall be a minimum of [***] US Dollars ($[***] USD) combined single limit coverage for each occurrence for bodily injury or for property damage and shall be provided from an insurance company qualified to write global product liability coverage. Each Party agrees, upon request, to furnish the other Party with a certificate of insurance evidencing such insurance coverage (at the execution of this Agreement and at each subsequent renewal) and shall provide the other Party

with a [***] ([***]) day notice of cancellation or non-renewal of such coverage. COMPANY shall provide its current certificate of insurance evidencing such insurance coverage as of the Effective Date. COMPANY shall name DPT as an additional insured on its insurance policies maintained pursuant to this Section 11.2.

11.3 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, OR ANY OTHER THEORY OR FORM OF ACTION, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, WITH RESPECT TO ALL CLAIMS MADE BY COMPANY AGAINST DPT UNDER THIS AGREEMENT, THE TOTAL LIABILITY OF DPT TO COMPANY DURING THE TERM SHALL NOT EXCEED [***] U.S. DOLLARS ($[***] USD), INCLUDING CLAIMS FOR INDEMNIFICATION FOR THIRD PARTY CLAIMS UNDER THIS ARTICLE 11 AND ANY COSTS TO BE REIMBURSED IN CONNECTION WITH ANY PRODUCT RECALL (OR CORRECTIVE ACTION) UNDER SECTION 4.4.5.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. The initial term of this Agreement shall commence on the Effective Date hereof and will continue until December 31 of the fourth (4^{th}) calendar year following Agreement ratification, unless sooner terminated pursuant to Section 12.2 below (the "**Initial Term**"). This Agreement shall thereafter automatically renew for periods of twenty-four (24) months, unless any Party shall give notice to the other to the contrary at least eighteen (18) months prior to the expiration of the Initial Term or any renewal term of the Agreement (such renewal term, the "**Extended Term**" and, together with the Initial Term, the "**Term**").

12.2 Termination. This Agreement may be terminated in its entirety by either Party at any time upon the occurrence of either of the following events:

12.2.1 The material failure of the other Party to comply with its material obligations herein, which failure is not remedied within sixty (60) days after written notice thereof.

12.2.2 Written notice to the other if any Bankruptcy Event has occurred with respect to such other Party.

12.3 Effects of Termination. In the event of the termination or cancellation of this Agreement for any reason, and without prejudice to any other rights and remedies available to DPT hereunder, COMPANY agrees to reimburse DPT, within [***] ([***]) days of such termination or cancellation, for: (i) the Materials Fee for all DPT-supplied materials ordered by DPT for the manufacture of Product based on COMPANY's Forecasted Needs, (ii) the Total Price per unit of Product, with a prorated adjustment for percent completed for work-in-process Product, and (iii) the Total Price per unit of Product for finished Product.

12.4 Nonexclusive Remedy. Exercise of any right of termination afforded to either Party under this Agreement (i) shall not prejudice any other legal rights or remedies either Party have against the other in respect of any breach of the terms and conditions of this Agreement, and (ii) shall be without any obligation or liability arising from such termination other than such obligations expressly arising from termination.

12.5 Survival. Termination of this Agreement (for any reason) shall not affect any accrued rights or liabilities of either Party. Article 1 (Definitions/Interpretation), Article 9 (Representations and Warranties), Article 10 (Confidentiality), Article 11 (Indemnification and Insurance), Article 13 (Disputes; Governing Law) and Article 14 (Miscellaneous), Sections 2.3.3 (Packaging and Labeling) (last sentence only), 3.4 (Destruction Costs), 4.4.5 (Product Recall), 6.4 (Obsolete Inventory), 12.3 (Effect of Termination), 12.4 (Nonexclusive Remedy) and 12.5 (Survival) shall survive the termination or cancellation of this Agreement.

ARTICLE 13
DISPUTES; GOVERNING LAW

13.1 Discussion by Executives. Except as otherwise provided herein, any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach hereof (and including the applicability of this Article 13 to any such dispute, controversy or claim) (each a "**Dispute**") shall be first submitted to an executive officer of each of the Parties having authority to resolve such Dispute for attempted resolution by good faith negotiations within [***] ([***]) Business Days. In such event, each Party shall cause its designated executive officer to meet and be available to attempt to resolve such issue. If the Parties should resolve such Dispute, a memorandum setting forth their agreement will be prepared and signed by both Parties if requested by either Party. The Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the Dispute.

13.2 Governing Law. This Agreement and all rights and obligations of the Parties arising out of or relating to this Agreement shall be governed by, construed and enforced in accordance with the laws of the State of Delaware, U.S.A without giving effect to conflicts of laws principles. The Parties hereby expressly agree that the U.N. Convention on Contracts for the International Sale of Goods shall not apply.

13.3 Jurisdiction. The Parties agree that any Dispute that is not resolved pursuant to Section 13.1 shall be subject to the exclusive jurisdiction of the state and federal courts in Delaware, U.S.A. and each Party hereby submits to such jurisdiction.

ARTICLE 14
MISCELLANEOUS

14.1 Relationship of the Parties. The Parties agree that the relationship of COMPANY and DPT established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, and nor shall this Agreement create or establish an employment, agency or any other relationship. Except as may be specifically

provided herein, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

14.2 Expenses. Except as otherwise expressly provided herein, each Party shall bear its own costs, fees and expenses incurred by such Party in connection with this Agreement.

14.3 Licenses and Permits. Each Party shall, at its sole cost and expense, maintain in full force and affect all necessary licenses, permits, and other authorizations required by Applicable Law in order to carry out its duties and obligations hereunder.

14.4 Force Majeure. No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement if, but only to the extent that such failure or delay is due to causes beyond the reasonable control of the affected Party, including: (a) acts of God; (b) fire, explosion, or unusually severe weather; (c) war, invasion, riot, terrorism, or other civil unrest; (d) governmental laws, orders, restrictions, actions, embargo or blockages; (e) national or regional emergency; (f) strikes or industrial disputes at a national level which directly impact the affected Party's performance under this Agreement; or (g) other similar cause outside of the reasonable control of such Party ("**Force Majeure**"); provided that the Party affected shall promptly notify the other of the Force Majeure condition and shall use reasonable efforts to eliminate, cure or overcome any such causes and resume performance of its obligations as soon as possible. If the performance of any such obligation under this Agreement is delayed owing to such a Force Majeure for any continuous period of more than one hundred eighty (180) days, DPT shall have the right to terminate this Agreement.

14.5 Notices. Any notice required or permitted to be given hereunder shall be in writing and shall be delivered in person, by a nationally recognized overnight courier, or by registered or certified airmail, postage prepaid to the addresses given below or such other addresses as may be designated in writing by the Parties from time to time, and shall be deemed to have been given upon receipt.

In the case of COMPANY:

Arcutis Biotherapeutics, Inc.
3027 Townsgate Rd, Suite 300
Westlake Village, CA 91361
ATTN: [***]

With a required copy to:

In the case of DPT:

DPT Laboratories, Ltd.
307 E. Josephine Street
San Antonio, TX 78215 U.S.A.
Attention: [***]

With a required copy to:

Viatris Inc.
1000 Mylan Boulevard
Canonsburg, PA 15317 U.S.A.
Attention: Global General Counsel

14.6 Assignment. Neither Party shall at any time, without obtaining the prior written consent of the other Party, assign or transfer this Agreement or subcontract its obligations hereunder to any Person. Notwithstanding the foregoing, DPT shall be permitted, without the consent of COMPANY, to assign this Agreement to its Affiliates or to perform this Agreement,

in whole or in part, through its Affiliates, and DPT may also assign this Agreement, without the consent of COMPANY, to any successor or Third Party that acquires all or substantially all of the assets to which this Agreement relates by sale, transfer, merger, reorganization, operation of law or otherwise; provided that the assignee agrees in writing to be bound to the terms and conditions of this Agreement. In the event of an assignment permitted under this Section 14.6, the assigning Party shall notify the other Party in writing of such assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their successors and permitted assigns. Any assignment not in accordance with this Section 14.6 shall be null and void.

14.7 Entire Agreement and Amendment. This Agreement (including, for clarity, its Schedules and Exhibits), constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. Notwithstanding the foregoing, except as expressly set forth in Section 2.6, to the extent the terms and conditions of the body of this Agreement conflict with the terms and conditions of any Schedule or Exhibit hereto, the terms and conditions of the body of this Agreement shall govern. No terms or provisions of this Agreement will be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

14.8 No Third Party Beneficiaries. Except for the rights to indemnification provided for under Article 11 above, all rights, benefits and remedies under this Agreement are solely intended for the benefit of DPT and COMPANY. Except for such rights to indemnification expressly provided pursuant to Article 11, no Third Party shall have any rights whatsoever to (a) enforce any obligation contained in this Agreement; (b) seek a benefit or remedy for any breach of this Agreement; or (c) take any other action relating to this Agreement under any legal theory, including actions in contract, tort (including negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

14.9 Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to negotiate in good faith a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

14.10 No Waiver. A waiver by any Party of any of the terms and conditions of this Agreement in any instance will not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

14.11 Compliance with Law. Both COMPANY and DPT shall perform their obligations under this Agreement in accordance with Applicable Law and each Party shall bear its own costs in ensuring compliance therewith. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement that violates, or which it reasonably believes may violate, any Applicable Law.

14.12 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.13 Review by Legal Counsel. Each Party agrees that it has read and had the opportunity to review this Agreement with its legal counsel. Accordingly, the rule of construction that any ambiguity contained in this Agreement shall be construed against the drafting Party shall not apply.

14.14 Further Acts. Each Party shall do, execute and perform and shall procure to be done and performed all such further acts, deeds, documents and things as the other Parties may reasonably require from time to time to give full effect to the terms of this Agreement.

14.15 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same document. This Agreement and any amendments hereto, to the extent signed and delivered by means of electronic reproduction (e.g., portable document format (.pdf)), shall be treated in all manner and respects as an original and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person. At the request of a Party, the other Party shall re-execute original forms thereof and deliver them to the Party who made said request.

[*The remainder of this page is left intentionally blank; signature page follows*.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

ARCUTIS BIOTHERAPEUTICS INC.
By: /s/ Todd Franklin Watanabe
Print Name: Todd Franklin Watanabe
Title: President, Chief Executive Officer and Director
Date: September 22, 2021

DPT Laboratories, Ltd.
By: /s/ Geoff Kindt
Print Name: Geoff Kindt
Title: Head of Site Operations
Date: September 17, 2021

Schedule A

API

API in the Roflumilast Cream, 0.3%

Ingredient	Amount (% w/w)	Function of Component
Roflumilast	0.3	Drug Substance

Schedule B

Product & Specifications

[***]

Schedule C

Fees

[***]

Schedule D

Territory

United States of America

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Todd Franklin Watanabe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcutis Biotherapeutics, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

By: /s/ Todd Franklin Watanabe

Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott L. Burrows, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcutis Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

By: /s/ Scott L. Burrows

Scott L. Burrows
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arcutis Biotherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and Scott L. Burrows, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2021 By: /s/ Todd Franklin Watanabe

Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 4, 2021 By: /s/ Scott L. Burrows

Scott L. Burrows
Chief Financial Officer
(Principal Accounting and Financial Officer)