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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 March 31, 2020
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)**
2945 Townsgate Road Suite 110 **Westlake Village, California** **(Address of Principal Executive Offices)**	**91361** **(Zip Code)**

(805) 418-5006
(Registrant's telephone number, including area code)

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 May 1, 2020 was 38,154,550.

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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)

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 190,893	$ 63,336
Marketable securities	58,426	37,929
Prepaid expenses and other current assets	4,559	5,209
Total current assets	253,878	106,474
Property, plant, and equipment, net	241	227
Operating lease right-of-use asset	226	264
Other assets	47	47
Total assets	$ 254,392	$ 107,012
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,759	$ 1,405
Accrued liabilities	7,281	3,654
Operating lease liability	182	178
Total current liabilities	12,222	5,237
Operating lease liability, noncurrent	82	129
Other long-term liabilities	206	184
Total liabilities	12,510	5,550
Commitments and contingencies (Note 6)		
Convertible preferred stock, $0.0001 par value; no shares and 48,787,898 shares authorized at March 31, 2020 and December 31, 2019, respectively; no shares and 24,385,388 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	166,491
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and no shares authorized at March 31, 2020 and December 31, 2019, respectively; no shares issued and outstanding at March 31, 2020 and December 31, 2019;	—	—
Common stock, $0.0001 par value; 300,000,000 and 65,820,000 shares authorized at March 31, 2020 and December 31, 2019, respectively; 38,154,550 and 2,879,763 shares issued at March 31, 2020 and December 31, 2019, respectively; 37,471,997 and 2,120,853 shares outstanding at March 31, 2020 and December 31, 2019, respectively	3	—
Additional paid-in capital	336,145	1,244
Accumulated other comprehensive income (loss)	19	(1)
Accumulated deficit	(94,285)	(66,272)
Total stockholders' equity (deficit)	241,882	(65,029)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 254,392	$ 107,012

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 March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 25,182	$ 6,203
General and administrative	3,469	749
Total operating expenses	28,651	6,952
Loss from operations	(28,651)	(6,952)
Other income, net	638	294
Net loss	$ (28,013)	$ (6,658)
Other comprehensive income (loss):		
Unrealized gain on marketable securities	20	1
Comprehensive loss	$ (27,993)	$ (6,657)
Per share information:		
Net loss per share, basic and diluted	$ (1.15)	$ (4.08)
Weighted-average shares used in computing net loss per share, basic and diluted	24,256,402	1,632,694

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	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2018	16,262,425	$ 72,252	1,557,900	$ —	$ 289	$ —	$ (24,276)	$ (23,987)
Vesting of founder shares subject to repurchase	—	—	68,931	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	65,868	—	29	—	—	29
Stock-based compensation expense	—	—	—	—	76	—	—	76
Unrealized gain on short term investments	—	—	—	—	—	1	—	1
Net Loss	—	—	—	—	—	—	(6,658)	(6,658)
Balance—March 31, 2019	16,262,425	$ 72,252	1,692,699	$ —	$ 394	$ 1	$ (30,934)	$ (30,539)

	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, 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, net of issuance costs of $16.0 million	—	—	10,781,250	1	167,240	—	—	167,241
Issuance 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 short term investments	—	—	—	—	—	20	—	20
Net Loss	—	—	—	—	—	—	(28,013)	(28,013)
Balance—March 31, 2020	—	$ —	37,471,997	$ 3	$ 336,145	$ 19	$ (94,285)	$ 241,882

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

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

	Three Months Ended March 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (28,013)	$ (6,658)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	27	5
Right-of-use asset amortization	38	19
Net amortization/accretion on marketable securities	(192)	(120)
Stock-based compensation	990	76
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,097)	(315)
Other assets	—	(47)
Accounts payable	3,412	(393)
Accrued liabilities	3,868	370
Operating lease liabilities	(43)	(11)
Net cash used in operating activities	(21,010)	(7,074)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(35,285)	(11,687)
Proceeds from maturities of marketable securities	15,000	2,600
Purchases of property and equipment	(41)	(183)
Net cash used in investing activities	(20,326)	(9,270)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	247	—
Proceeds from initial public offering, net of issuance costs	168,646	—
Net cash provided by financing activities	168,893	—
Net increase (decrease) in cash and cash equivalents	127,557	(16,344)
Cash and cash equivalents at beginning of period	63,336	39,394
Cash and cash equivalents at end of period	$ 190,893	$ 23,050
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Right-of-use asset obtained in exchange for lease liability	$ —	$ 391
Deferred financing costs included in accounts payable and accrued liabilities	$ 4	$ —

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 and commercializing treatments for dermatological diseases with high unmet medical needs. The Company's current portfolio is comprised of topical treatments with significant promise in addressing immune-mediated dermatological diseases and conditions, or immuno-dermatology. The Company's strategy is to advance treatments that leverage validated biological targets in dermatology in order to deliver clinical profiles that address 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

On January 31, 2020, the Company completed 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. The financial statements as of March 31, 2020, including share and per share amounts, incorporate the effects of the IPO.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $94.3 million and $66.3 million as of March 31, 2020 and December 31, 2019, respectively. The Company had cash, cash equivalents and marketable securities of $249.3 million and $101.3 million as of March 31, 2020 and December 31, 2019, respectively. Prior to selling common stock in its IPO, 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 May 12, 2020, the Company's operations have not been significantly impacted by the COVID-19 pandemic. The Company is monitoring the potential 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.

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

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, or U.S. GAAP.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the 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 March 31, 2020, the interim condensed statements of operations and comprehensive loss, the condensed changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for the three months ended March 31, 2020 and 2019 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-month periods are also unaudited. The condensed results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2019 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, 2019.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of money market funds, commercial paper, and government securities.

Marketable Securities

Marketable securities consist of investment grade short to intermediate-term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase are classified as current based on their availability for use in current operations.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses as well as credit losses, if any, on marketable securities are included in other income (expense), 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. As of March 31, 2020, there were unrealized gains on marketable securities of $19,000 and as of December 31, 2019, there were unrealized losses on marketable securities of $1,000. Unrealized gains and losses on marketable securities are reported as a component of Accumulated Other Comprehensive Income (Loss) on the balance sheet. There were no realized gains or losses on investments for the three months ended March 31, 2020 and 2019. Interest on marketable securities is included in Other income (expense), net.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the balance sheets.

Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 3 *Fair Value Measurements*, include cash equivalents, accounts payable and accrued liabilities. The carrying amount of cash equivalents, accounts payable and accrued liabilities approximate their fair values due to their short maturities.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active;

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Leases

The Company leases a facility with a non-cancelable lease term of 30 months. The term of the lease includes a renewal option at the election of the Company to extend the lease for an additional term. The renewal option has not been considered in the determination of the right-of-use, or ROU, asset or lease liability as the Company did not consider it reasonably certain it would exercise this option.

The Company determines if an arrangement is or contains a lease at inception. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The classification of the Company's leases as operating or finance leases along with the initial measurement and recognition of the associated ROU assets and lease liabilities is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. The Company uses its incremental borrowing rate, based on the information available at commencement date, to determine the present value of lease payments when its leases do not provide an implicit rate. The Company uses the implicit rate when readily determinable. The ROU asset is based on the measurement of the lease liability, includes any lease payments made prior to or on lease

commencement and excludes lease incentives and initial direct costs incurred, as applicable. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term. The Company considers a lease term to be the 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 agreement includes lease and non-lease components and the Company has elected to not separate such components. Further, the Company elected the short-term lease exception policy, permitting it to not apply the recognition requirements of this standard to leases with terms of 12 months or less (short-term leases) for all classes of assets.

Preclinical and Clinical Accruals and Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical 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 months ended March 31, 2020 and 2019, 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 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 January 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

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

The Company accounts for share-based payments at fair value. The fair value of stock options is measured using the Black-Scholes option-pricing model. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for such awards is the date of grant and the expense is recognized on a straight-line basis, over the expected vesting period. For share-based awards that vest subject to a performance condition, the Company will recognize compensation cost for awards if and when the Company concludes that it is probable that the awards with a performance condition will be achieved on an accelerated attribution method. The Company accounts for forfeitures as they occur.

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the 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 Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted by the United States Congress on March 27, 2020. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of COVID-19. The CARES Act includes modifications to the limitations on business interest expense and net operating loss provisions and provides a payment delay of employer payroll taxes during 2020 after the date of enactment. The Company does not expect the CARES Act 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, or VIE. If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that entity. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (i) the power to direct the economically significant activities of the entity and (ii) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If the Company determines it is the primary beneficiary of a VIE, it consolidates that VIE into the Company's financial statements. The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation or deconsolidation event. 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.

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

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

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* or ASU No. 2018-13, which removes, modifies, and adds various disclosure requirements on fair value measurements in Topic 820. ASU No. 2018-13 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company adopted this standard as of January 1, 2020, and it did not have a material impact on its condensed financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* or ASU No. 2016-13*.* This update requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Financial institutions and other organizations now include forward-looking information in the determination of their credit loss estimates. Many of the previous loss estimation techniques are still permitted, although the inputs to those techniques have changed to reflect the full amount of expected credit losses. In addition, this update amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. The Company adopted this standard as of January 1, 2020, and it did not have a material impact on its condensed financial statements. There was no impact on the Company's condensed financial statements from credit losses for the three months ended March 31, 2020.

In December 2019, the FASB issued ASU No. 2019-12*, Income Taxes (Topic 740)* which amends the existing guidance relating to the accounting for income taxes. This standard is intended to simplify the accounting for income taxes by removing certain exceptions to the general principles of accounting for income taxes and to improve the consistent application of GAAP for other areas of accounting for income taxes by clarifying and amending existing guidance. The standard is effective for public business entities for fiscal years beginning after December 15, 2020, and interim periods therein. Early adoption is permitted. An entity that elects early adoption in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. Additionally, an entity that elects early adoption should adopt all the amendments in the same period. The Company early adopted this guidance as of January 1, 2020, and it did not have a material impact on its 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):

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

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$ 190,893	$ —	$ —	$ 190,893
Commercial paper	—	53,396	—	53,396
Government securities	5,030	—	—	5,030
Total assets	$ 195,923	$ 53,396	$ —	$ 249,319

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$ 43,558	$ —	$ —	$ 43,558
Commercial paper	—	44,689	—	44,689
Government securities	13,018	—	—	13,018
Total assets	$ 56,576	$ 44,689	$ —	$ 101,265

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

Commercial paper, money market funds and government securities are valued taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

The following 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):

	March 31, 2020			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds(1)	$ 190,893	$ —	$ —	$ 190,893
Total cash and cash equivalents	190,893	—	—	190,893
Marketable securities:				
Commercial paper	$ 53,396	—	—	$ 53,396
Government securities	5,011	19	—	5,030
Total marketable securities	$ 58,407	$ 19	$ —	$ 58,426

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

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	December 31, 2019			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Commercial paper	$ 11,780	$ —	$ —	$ 11,780
Money market funds(1)	43,558	—	—	43,558
Government securities	7,998	—	—	7,998
Total cash and cash equivalents	63,336	—	—	63,336
Marketable securities:				
Commercial paper	32,909	—	—	32,909
Government securities	5,021	—	(1)	5,020
Total marketable securities	$ 37,930	$ —	$ (1)	$ 37,929

There were no realized gains or losses on investments for the three months ended March 31, 2020 and 2019. As of March 31, 2020 and December 31, 2019, unrealized losses on marketable securities were not material, and accordingly, no allowance for credit losses was recorded as of March 31, 2020. As of March 31, 2020 and December 31, 2019, all securities have a maturity of one year or less and all securities with gross unrealized losses have been in continuous loss position for less than twelve months.

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	March 31, 2020	December 31, 2019
Prepaid insurance	$ 2,326	$ 62
Prepaid clinical trial costs	1,583	2,998
Deferred financing costs	—	1,747
Other prepaid expenses and current assets	650	402
Total prepaid expenses and other current assets	4,559	5,209

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2020	December 31, 2019
Clinical trial accruals	$ 6,114	$ 1,497
Accrued compensation	806	1,379
Early exercise liability, current	269	225
Accrued expenses and other current liabilities	92	553
Total accrued liabilities	$ 7,281	$ 3,654

5. License Agreements

AstraZeneca License Agreement

In July 2018, the Company entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca AB, or AstraZeneca, granting the Company a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and

regulatory documentation, to research, develop, manufacture, 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 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 topical roflumilast cream (ARQ-151) 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 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 months ended March 31, 2020 and 2019.

Hengrui Exclusive Option and License Agreement

In January 2018, the Company entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, whereby Hengrui granted the Company an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK 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 million in sales-based milestones based on certain aggregate annual net sales volumes with respect to a licensed product.

With respect to any products the Company commercializes under the Hengrui License Agreement, it will pay tiered royalties to Hengrui on net sales of each licensed product by the Company, or its affiliates, or its sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the later of (1) expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, the Company is obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income it receives from sublicensees of its rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

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There were no payments made or due in connection with Hengrui for the three months ended March 31, 2020 and 2019.

Hawkeye Collaboration Agreement

In June 2019, the Company entered into a collaboration agreement, or Hawkeye Agreement, with Hawkeye Therapeutics, Inc., or Hawkeye, a related party with common ownership, 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 variable interest entity for which consolidation is not required as it is not the primary beneficiary.

6. Commitments and Contingencies

Operating Lease

The Company leases one facility in Westlake Village, California under an operating lease that commenced in February 2019 and has a non-cancelable lease term of 30 months, subject to fixed escalation increases.

The minimum annual rental payments of the Company's operating lease liability as of March 31, 2020 are as follows (in thousands):

	Amounts
2020 (April through December)	$ 145
2021	132
Total minimum lease payments	$ 277
Less: Amounts representing interest	(13)
Present value of future minimum lease payments	$ 264
Current portion operating lease liability	$ 182
Operating lease liability, noncurrent	82
Total operating lease liability	$ 264

Straight-line rent expense recognized for operating leases was $43,000 and $24,000 for the three months ended March 31, 2020 and 2019, respectively . There were no variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the three months ended March 31, 2020 and 2019.

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

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities		
Cash paid for amounts included in the measurement of lease liabilities	$ 47	$ 16

The following summarizes additional information related to the operating lease:

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	March 31, 2020
Weighted-average remaining lease term (in years)	1.42
Weighted-average discount rate	7.0 %

In April 2020, the Company amended its lease agreement. See Note 10.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by California corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

7. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Convertible preferred stock as of December 31, 2019 consisted of the following (in thousands, except share amounts):

Convertible Preferred Stock	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Liquidation Preference
Series A	13,800,000	6,897,575	$ 14,340	$ 13,800
Series B	18,736,270	9,364,850	57,912	58,000
Series C	16,251,628	8,122,963	94,239	94,500
Total	48,787,898	24,385,388	$ 166,491	$ 166,300

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

In October 2019, the Company issued 8,122,963 shares of Series C convertible preferred stock at a purchase price of $11.63 per share for total gross proceeds of $94.5 million, some of which were to related parties.

In September 2018, the Company issued 9,364,850 shares of Series B convertible preferred stock at a purchase price of $6.19 per share for total proceeds of $57.9 million, some of which were to related parties.

In April 2017, the Company entered into a Stock Purchase Agreement with investors, some of which were related parties, to issue 5,398,111 shares of Series A convertible preferred stock at $2.00 per share in three tranches. The first tranche, consisting of 3,590,845 shares for net proceeds of $7.1 million, was completed upon execution of the agreement. Additionally, the Company issued 149,946 shares of Series A convertible preferred stock as a result of the conversion of convertible promissory notes with an outstanding principal amount of $154,000 and the settlement of the derivative liability of $150,000.

The Series A investors were also granted freestanding rights to participate in additional tranches to raise a minimum of $3.3 million, upon election by the board of directors including at least one of the Series A directors, by purchasing 1,657,314 shares of Series A convertible preferred stock at $2.00 per share in two tranches, provided such election occurred prior to April 2019. The two tranches consisted of 828,654 shares and 828,660 shares,

respectively. The Company concluded that the investors' rights to purchase Series A convertible preferred shares met the definition of a freestanding financial instrument, as they were legally detachable and separately exercisable from the Series A convertible preferred stock, or the Series A Convertible Preferred Stock Liability. As the Series A Convertible Preferred Stock Liability was redeemable at the election of holders of the then-outstanding shares, it represented a liability to be accounted for at fair value and remeasured at each reporting period.

Changes in fair value were recognized as a gain or loss in other income (expense), net in the statement of operations. On the closing of the first tranche in April 2017, the Company recorded the initial fair value of the Series A Convertible Preferred Stock Liability of $219,000 for the second and the third tranche participating rights by reducing the carrying value of Series A convertible preferred stock.

In March 2018, the Company completed the second tranche closing and issued 3,156,784 shares of Series A convertible preferred stock to the investors at a purchase price of $2.00 per share for net proceeds of $6.3 million. The Series A Convertible Preferred Stock Liability was remeasured to fair value just prior to settlement and the carrying value of the liability of $891,000 was reclassified to Series A convertible preferred stock. Concurrently with the closing of the second tranche, the Company amended the Series A convertible preferred stock purchase agreement to merge the second and third tranches and increased the maximum number of shares to be issued in the second tranche to 3,156,784 shares.

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 March 31, 2020, no dividends had been declared by the Board of Directors.

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

	March 31, 2020	December 31, 2019
Convertible preferred stock outstanding	—	24,385,388
Options issued and outstanding	3,061,521	2,516,470
Common stock awards available for grant under employee benefit plans	3,251,890	1,550,150
Restricted stock units outstanding	130,060	—
Total common stock reserved	6,443,471	28,452,008

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 March 31, 2020 and December 31, 2019.

8. Stock-Based Compensation

In January 2020, the Company's board of directors approved the 2020 Equity Incentive Plan, or the 2020 Plan, which became effective upon the completion of the IPO on January 31, 2020. The 2020 Plan serves as the successor incentive award plan to the Company's 2017 Equity Incentive Plan, or the 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 lapse 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, 2021

and each subsequent anniversary 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. As of March 31, 2020, the Company had 2,900,890 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.

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, 2019	2,516,470		$ 3.47	9.44	$ 7,673
Granted	653,200		$ 26.92		
Exercised	(108,149)		$ 2.30		
Balance—March 31, 2020	3,061,521		$ 8.52	9.35	$ 65,155
Exercisable—March 31, 2020	1,686,893	(1)	$ 5.85	9.24	$ 40,408

(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 March 31, 2020. As of December 31, 2019, prior to the Company's IPO, 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 three months ended March 31, 2020 was $1.5 million.

The total grant-date fair value of the options vested during the three months ended March 31, 2020 was $367,000. The weighted-average grant-date fair value of employee options granted during the three months ended March 31, 2020 was $16.94.

Restricted Stock Unit Activity

The following table summarizes information regarding our restricted stock units (RSUs):

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2019	—	$ —
Granted	130,060	$ 27.61
Vested	—	$ —
Forfeited	—	$ —
Unvested Balance—March 31, 2020	130,060	$ 27.61

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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 4 years. There were no RSU grants prior to January 1, 2020.

Stock-Based Compensation Expense

Stock-based compensation expense recognized in our Condensed Statements of Operations and Comprehensive Loss was as follows (in thousands):

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 416	$ 31
General and administrative	574	45
Total stock-based compensation expense	$ 990	$ 76

As of March 31, 2020, there was $15.8 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 3.4 years. As of March 31, 2020, there was $3.6 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 3.9 years.

In determining the fair value of the stock options granted, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

Fair value of common stock— 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; and (vi) equity market conditions affecting comparable public companies; (vii) general U.S. market conditions; and (viii) the lack of marketability of the Company's common stock. 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—Since the Company does not have sufficient trading history for its common stock, the expected volatility was estimated based on the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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

Dividend Yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

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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:

	Three Months Ended March 31, 2020	Year Ended December 31, 2019
Expected term (in years)	5.5 – 6.1	5.1 – 6.6
Expected volatility	71.2 – 73.3%	68.6 – 72.5%
Risk-free interest rate	0.5 – 1.4%	1.6 – 2.6%
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. Such shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $475,000 and $409,000 as a liability from the early exercise in the accompanying balance sheet as of March 31, 2020 and December 31, 2019, respectively. As of March 31, 2020 and December 31, 2019, there were $269,000 and $225,000 recorded in accrued liabilities, respectively, and $206,000 and $184,000 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 vest under a service condition and 84,835 shares vest under a performance condition. The shares were issued under the terms of the respective restricted stock purchase agreements, or the Stock Purchase Agreement, and unvested shares are subject to repurchase by the Company at the original purchase price per share upon the holder's termination of his relationship with the Company. The restricted shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. One-fourth of the 1,102,903 shares of restricted common stock were vested on the first-anniversary date and the remaining 827,177 shares will vest on a monthly basis thereafter. In July 2018, performance conditions prescribed by the Stock Purchase Agreement were met and 84,835 shares of the restricted common stock were fully vested. During the three months ended March 31, 2020 and 2019, 68,931 shares and 68,931 shares of restricted common stock were vested, respectively. As of March 31, 2020, 68,932 shares of restricted stock are unvested.

2020 Employee Stock Purchase Plan

The Company adopted the 2020 Employee Stock Purchase Plan, or the ESPP, which became effective upon the completion of the IPO on January 31, 2020. 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. The Company commenced an offering period on January 31, 2020.

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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.

9. 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 March 31,	
	2020	**2019**
Convertible preferred stock on an as-converted basis	—	16,262,425
Stock options to purchase common stock	3,061,521	1,461,191
Early exercised options subject to future vesting	613,627	578,298
Restricted stock subject to future vesting	198,992	344,657
ESPP shares subject to future issuance	11,392	—
Total	3,885,532	18,646,571

10. Subsequent Event

In April 2020, the Company amended its lease agreement for its facility in Westlake Village, California to relocate to a new expanded space comprising 22,643 square feet. The lease will begin when the tenant improvements are substantially complete and terminates 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 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 1 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 provides for a tenant improvement allowance up to $1.25 million. It also requires the Company to have an available letter of credit of $1.5 million upon commencement, which is allowed to be reduced throughout the lease period as rent obligations are met.

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, 2019 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, 2019, which has been filed with the Securities and Exchange Commission. 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 and commercializing treatments for dermatological diseases with high unmet medical needs. Our current portfolio is comprised of topical treatments with significant potential to address immune-mediated dermatological diseases and conditions, or immuno-dermatology. Our strategy is to identify and develop treatments against validated biological targets in dermatology that deliver a differentiated clinical profile that addresses major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product candidate, topical roflumilast cream (ARQ-151), is in Phase 3 clinical trials in plaque psoriasis. Roflumilast cream is a topical cream formulation of roflumilast, a highly potent and selective phosphodiesterase type 4, or PDE4, inhibitor, which we are developing for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. In July 2018, we executed a worldwide licensing agreement with AstraZeneca AB, or AstraZeneca, for exclusive worldwide rights to all topical dermatological uses of roflumilast. We have successfully completed a Phase 2b study of roflumilast cream in plaque psoriasis, and, in August 2019, paid AstraZeneca the first milestone payment of $2.0 million that was earned upon the achievement of positive Phase 2 data for any AZ-Licensed Product (as defined in "—License Agreements—AstraZeneca License Agreement"). We have initiated three Phase 3 studies in plaque psoriasis, including two pivotal studies (DERMIS-1 and DERMIS-2) and an open label extension study (DERMIS-OLE), with topline data expected in the first half of 2021. We also completed a Phase 2 proof of concept study of roflumilast cream in atopic dermatitis (AD) and plan to initiate a Phase 2b study in AD in the second half of 2020, with topline results expected in the second half of 2021. In addition, we are developing ARQ-154, a topical foam formulation of roflumilast cream, and have initiated a Phase 2 proof of concept study in seborrheic dermatitis and a Phase 2b study in scalp psoriasis. We expect to report topline data in the second half of 2020 with respect to seborrheic dermatitis and in Q4 2020/Q1 2021 with respect to scalp psoriasis.

Beyond this, we also began enrolling patients in the safety cohort of a Phase1/2b study of ARQ-252, a potent and highly selective topical janus kinase type 1, or JAK1, inhibitor for the treatment of chronic hand eczema, and will begin enrolling the efficacy cohort in the second half of 2020, with topline data expected in the second half of 2021. We also plan to initiate a Phase 2a study of ARQ-252 in vitiligo in the second half of 2020. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. In January 2018, we executed an exclusive option and license agreement with Jiangsu Hengrui Medicine Co., Ltd. of China, or Hengrui, to the active pharmaceutical ingredient in ARQ-252 and ARQ-255 for all topical formulations for dermatological uses in the United States, Canada, Europe and Japan. In December 2019, we exercised our exclusive option associated with

this 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.

Since our inception in 2016, we have invested a significant portion of our efforts and financial resources in research and development activities. We have not generated any revenue from product sales and, prior to our IPO completed in January 2020, have funded our operations primarily with $162.5 million in net cash proceeds from private placements of our convertible preferred stock. On January 31, 2020, we completed 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.

We have incurred net losses in each year since inception, including net losses of $28.0 million and $6.7 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020 and December 31, 2019, we had an accumulated deficit of $94.3 million and $66.3 million, respectively, and cash, cash equivalents and marketable securities of $249.3 million and $101.3 million, respectively.

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 unaudited condensed financial statements for additional information. Based on our current planned operations, we expect our current cash, cash equivalent, and marketable securities will be sufficient to fund our operations through 2021.

We rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our product candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, many of whom are single-source suppliers, for our preclinical and clinical trial materials, as well as the commercial supply of our products. In addition, we do not yet have a sales organization or commercial infrastructure. Accordingly, we expect to incur significant expenses to 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 global novel coronavirus disease 2019 (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 potential 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, topical roflumilast foam (ARQ-154) and ARQ-252. 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 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 an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca, granting us a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, commercialize and otherwise exploit products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, the AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. Under this agreement, we have sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at our expense, and we shall use commercially reasonable efforts 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 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 5 to the unaudited condensed financial statements for additional information.

Hengrui Exclusive Option and License Agreement

In January 2018, we entered into an exclusive option and license agreement, or Hengrui License Agreement, with Hengrui, whereby Hengrui granted us an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK 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. See Note 5 to the unaudited condensed financial statements for additional information.

Hawkeye Collaboration Agreement

In June 2019, we entered into a collaboration agreement, or the Hawkeye Agreement, with Hawkeye Therapeutics, Inc., or Hawkeye, a related party with common ownership, to collaborate on the research and development of one or more new applications of roflumilast. The Hawkeye Agreement grants Hawkeye an exclusive license to certain intellectual property developed under the agreement as it relates to the applications.

Contemporaneously with the execution of the Hawkeye Agreement, we entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye's common stock at $0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye. See Note 5 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 to our product candidates; internal costs are not allocated to specific product candidates.

We expect to continue to incur substantial research and development expenses in the future as we develop our product candidates. In particular, we expect to incur substantial research and development expenses for the Phase 3 trials (DERMIS-1 and DERMIS 2) of roflumilast cream for plaque psoriasis, the preclinical studies and clinical trials for the continued development of roflumilast cream for atopic dermatitis, roflumilast foam for seborrheic dermatitis and scalp psoriasis, ARQ-252 for hand eczema and vitiligo, and ARQ-255 for alopecia areata.

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

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of 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 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 Securities and Exchange Commission requirements, directors and officers liability insurance premiums and investor relations activities.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income earned on our marketable securities.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

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

	Three Months Ended March 31,		Change	
	2020	2019	$	%
	(unaudited) (in thousands)			
Operating expenses:				
Research and development	$ 25,182	$ 6,203	$ 18,979	306 %
General and administrative	3,469	749	2,720	363 %
Total operating expenses	$ 28,651	$ 6,952	$ 21,699	312 %
Loss from operations	(28,651)	(6,952)	(21,699)	312 %
Other income, net	638	294	344	117 %
Net loss	$ (28,013)	$ (6,658)	$ (21,355)	321 %

Research and Development Expenses

	Three Months Ended March 31,		Change	
	2020	2019	$	%
	(unaudited) (in thousands)			
Direct Costs:				
Preclinical and clinical	$ 18,736	$ 4,326	$ 14,410	333 %
Manufacturing	3,254	692	2,562	370 %
Indirect Costs:				
Compensation and personnel-related	2,267	823	1,444	175 %
Other	925	362	563	156 %
Total research and development expense	$ 25,182	$ 6,203	$ 18,979	306 %

Research and development expenses increased by $19.0 million, or 306%, for the three months ended March 31, 2020 compared to the three months ended March 31, 2019. The increase was due to an increase in clinical trial costs of $14.4 million, an increase in manufacturing costs of $2.6 million, an increase in compensation and personnel-related expenses of $1.4 million, and an increase of $0.6 million in other costs, including regulatory, research and clinical consulting costs. The increases in clinical trial costs and manufacturing costs, and the increase in the corresponding consulting costs, relate to new and ongoing studies of roflumilast cream, including three Phase 3 studies of roflumilast cream for plaque psoriasis and a Phase 1 pediatric study of roflumilast cream for atopic dermatitis. Additionally, there were new and ongoing costs related to the Phase 2b study of roflumilast foam for scalp psoriasis and a Phase 2 Proof of Concept clinical trial of roflumilast foam for seborrheic dermatitis. The increase in compensation and personnel-related expenses, which includes stock compensation, was primarily due to an increase in headcount.

General and Administrative Expenses

General and administrative expenses increased by $2.7 million, or 363%, for the three months ended March 31, 2020 compared to the three months ended March 31, 2019. The increase was primarily due to an increase in compensation and personnel-related expenses of $1.4 million, an increase in professional services of $0.7 million, and an increase in insurance costs of $0.5 million. The increase in compensation and personnel-related expenses, which includes stock compensation, was due to an increase in headcount. The increases in professional services, which includes accounting and audit fees of $0.3 million, and insurance costs were mainly due to the costs associated with being a public company.

Other Income, Net

Other income, net increased by $0.3 million, or 117%, for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 . The increase was primarily due to interest earned on our marketable securities from the funds received from our IPO in February 2020 and from the issuance of our Series C convertible preferred stock in the year ended December 31, 2019.

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 March 31, 2020 and December 31, 2019, we had cash, cash equivalents and marketable securities of $249.3 million and $101.3 million, respectively, and an accumulated deficit of $94.3 million and $66.3 million, respectively. 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 will continue to be dependent upon equity, debt financing or collaborations or other forms of capital at least until we are able to generate positive cash flows from our operations.

Cash Flows

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

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Cash used in operating activities	$ (21,010)	$ (7,074)
Cash used in investing activities	(20,326)	(9,270)
Cash provided by financing activities	168,893	—
Net increase (decrease) in cash and cash equivalents	$ 127,557	$ (16,344)

Net Cash Used in Operating Activities

During the three months ended March 31, 2020, net cash used in operating activities was $21.0 million, which consisted of a net loss of $28.0 million, offset by a change in net operating assets and liabilities of $6.1 million and net non-cash charges of $0.9 million. The change in net operating assets and liabilities was due to an increase of $7.3 million in accounts payable and accrued liabilities due to our overall growth, increased research and development spending and timing of payments, partially offset by an increase of $1.1 million in prepaid expenses and other current assets for premiums paid on insurance policies and other advances made for clinical trial costs. The net non-cash charges were primarily related to stock-based compensation expense of $1.0 million.

During the three months ended March 31, 2019, net cash used in operating activities was $7.1 million and consisted primarily of a net loss of $6.7 million and a change in our net operating assets and liabilities of $0.4 million. The change in net operating assets and liabilities was primarily due to an increase of $0.4 million in prepaid expenses and other assets for advances made for clinical trial costs and manufacturing.

Net Cash Used in Investing Activities

During three months ended March 31, 2020, net cash used in investing activities was $20.3 million, which was comprised primarily of purchases of marketable securities of $35.3 million, partially offset by proceeds from the maturities of marketable securities of $15.0 million.

During the three months ended March 31, 2019, net cash used in investing activities was $9.3 million, which was comprised primarily of purchases of marketable securities of $11.7 million, partially offset by proceeds from maturities of marketable securities of $2.6 million.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2020, net cash provided by financing activities was $168.9 million, which was comprised primarily of the net cash proceeds received from the IPO of $168.6 million.

During the three months ended March 31, 2019, there were no financing activities.

Funding Requirements

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $94.3 million and $66.3 million as of March 31, 2020 and December 31, 2019, respectively. We had cash, cash equivalents and marketable securities of $249.3 million and $101.3 million as of March 31, 2020 and December 31, 2019, respectively. Based on our current planned operations, we expect that our current cash, cash equivalents and marketable securities will be sufficient to fund our operations through 2021. 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 currently ongoing Phase 3 studies (DERMIS-1 and DERMIS 2) of roflumilast cream in plaque psoriasis, our planned Phase 2b study of roflumilast cream in atopic dermatitis, our currently ongoing Phase 2 proof of concept study of roflumilast foam in seborrheic dermatitis, our currently ongoing Phase 2b study of roflumilast foam in scalp psoriasis, our currently ongoing Phase 1/2b study of ARQ-252 in hand eczema, our planned Phase 2a study of ARQ-252 in vitiligo and our formulation and preclinical efforts for ARQ-255 for alopecia areata.
- 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

In April 2020, we amended our lease agreement for its facility in Westlake Village, California to relocate to a new expanded space including 22,643 square feet. The lease will begin when the tenant improvements, the allowance for which is up to $1.25 million, are substantially complete and terminates 91 months thereafter, with a renewal option for a term of 5 years. We will 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 1 year. The amended lease agreement provides for a tenant improvement allowance up to $1.25 million. It also requires that we deliver a letter of credit to the landlord of $1.5 million upon commencement, which is allowed to be reduced throughout the lease period as rent obligations are met.

There were no other material changes to our contractual obligations and contingent liabilities as described under the Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2019.

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, 2019. There were no material changes to our critical accounting policies during the three months ended March 31, 2020.

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

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

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 March 31, 2020, we had cash and cash equivalents of $190.9 million and marketable securities of $58.4 million, which consist of bank deposits, money market funds, commercial paper and government securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of March 31, 2020.

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 March 31, 2020. 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 Securities and Exchange Commission’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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to

apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2020, our CEO and CFO have concluded that, as of March 31, 2020, 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 three months ended March 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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, 2019. 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 complete later-stage clinical trials, obtain regulatory approvals, manufacture a drug on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization.

Our net loss for the three months ended March 31, 2020 and 2019 was approximately $28.0 million and $6.7 million, respectively. As of March 31, 2020, we had an accumulated deficit of $94.3 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. We may never achieve profitability and, even if we do, we may not be able to sustain profitability in subsequent periods. We

will continue to incur significant research and development and other expenses related to our ongoing operations and the development of our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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 March 31, 2020, we had capital resources consisting of cash, cash equivalents and marketable securities of $249.3 million. Based on our planned operations, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations through 2021. 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 currently ongoing Phase 3 clinical trials of roflumilast cream in plaque psoriasis, our planned Phase 2b study of roflumilast cream in atopic dermatitis, our currently ongoing Phase 2 proof of concept study of roflumilast foam in seborrheic dermatitis, our currently ongoing Phase 2b study of roflumilast foam in scalp psoriasis, our currently ongoing Phase 1/2b study of ARQ-252 in hand eczema, our planned Phase 2a study of ARQ-252 in vitiligo and our formulation and preclinical efforts for ARQ-255 in alopecia areata;
- 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, Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, or any future collaboration or licensing partners upon the achievement of negotiated milestones;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products, if any.

Adequate additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis or on attractive terms, we may be required to reduce our workforce, delay, limit, reduce or terminate our research and development activities, preclinical studies, clinical trials or other development activities and future commercialization efforts, or grant rights to develop and market product candidates, such as 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. Food and Drug Administration, or FDA, guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies, which may include obligations to make significant upfront and milestone payments;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on CROs and third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates both within and outside of the United States;

- our ability to establish and maintain collaborations, licensing or other arrangements with respect to our product candidates;
- our ability to maintain and enforce our intellectual property position;
- costs related to and outcomes of potential litigation or other disputes in respect of our product candidates and our business;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

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

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

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot assure you of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this 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 cream for the treatment of scalp psoriasis and seborrheic dermatitis, ARQ-252, a potent and highly selective topical JAK1 inhibitor for the treatment of chronic hand eczema, and ARQ-255, a potential topical treatment for alopecia areata. We currently do not have a drug discovery or research and development effort to discover new product candidates, and we have no intention to develop one. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of these current product candidates. We expect to conduct most of our clinical trials in the United States and Canada, with current limited plans for clinical trials in Australia and the European Union. We currently anticipate seeking regulatory approvals in the United States and Canada, but may in the future be subject to additional foreign regulatory authorities and may out-license our product candidates or approved products, if any, in additional foreign markets. In the future, we may also become dependent on other product candidates that we may acquire or in-license. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate, 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 current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, our Phase 2 proof of concept study in atopic dermatitis had a limited number of patients and it did not reach statistical significance for the primary endpoint or the secondary endpoint of IGA Success, which we expect will be the primary endpoint in any registrational trial, but did show significance in certain secondary efficacy endpoints. While we believe this is evidence of the ability of roflumilast cream to treat the signs and symptoms of atopic dermatitis, these results may not be replicated or improved in later studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. For example, we are developing roflumilast foam, including ongoing Phase 2 clinical trials in patients with seborrheic dermatitis and in patients with scalp psoriasis, based on our clinical experience with roflumilast cream in psoriasis. Despite our observations of roflumilast cream in a similar dermatological indication, roflumilast foam may not demonstrate comparable results in seborrheic dermatitis or scalp psoriasis. In addition, given its different formulation there is a risk that we selected an incorrect dose for roflumilast foam, as the clinical effect of roflumilast foam may differ from roflumilast cream at a similar dosing level or we may observe unexpected side effects not previously observed with roflumilast cream.

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 institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities

resulting in the imposition of a clinical hold, unforeseen safety issues or side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

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

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

Our lead product candidate, roflumilast cream, and roflumilast foam, its foam formulation, are currently in clinical development. Our product candidate ARQ-252 has just entered clinical development for chronic hand eczema and will do so in the second half of 2020 for vitiligo. ARQ-255 is in formulation and preclinical development for the potential treatment of alopecia areata. We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize our lead product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions, including pricing approval in the European Union.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates is safe and effective for the requested indication;
- the FDA or other relevant foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our 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 contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact our clinical trials and ability to obtain market approvals;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant foreign regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant foreign regulatory authority, as the case may be, require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant foreign regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant foreign regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant foreign regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates;
- the FDA or other relevant foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant foreign regulatory authorities may change their approval policies or adopt new regulations.
- the FDA's or the applicable foreign regulatory authority's non-approval of the formulation, dosing, labeling or specifications;
- the FDA's or the applicable foreign regulatory authority's failure to approve the manufacturing processes of third-party manufacturers upon which we rely or the failure of the facilities of our third-party manufacturers to maintain a compliance status acceptable to the FDA or the applicable foreign regulatory authority; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such

results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects.

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

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

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

Patient reported outcome instruments, their use in our Phase 3 clinical 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 is based on the percentage of patients achieving a score of "clear" or "almost clear" plus at least a 2-grade improvement from baseline on the 5 point Investigator's Global Assessment (or IGA) scale, referred to as "IGA Success". Success in our Phase 3 clinical trials, or other clinical trials with these or similar endpoints, requires the enrollment of patients with conditions that are severe enough to facilitate a two-grade improvement in the IGA scale, but not so severe that they cannot achieve a "clear"

or “almost clear” in IGA score in light of the severity of their disease. It is therefore possible that we enroll patients with conditions so severe that they do not or are unable to realize an IGA of 0 (clear) or 1 (almost clear) during the period covered by the clinical trial. As a result, there is no guarantee that our Phase 3 clinical trials will produce the same statistically significant results in “IGA Success”, which will serve as the primary endpoint, as our Phase 2b clinical trial, and there can be no guarantee that the characteristics of the population enrolled in our Phase 3 clinical trials does not adversely impact the results reported for such trial, any of which could have an adverse effect on our ability to secure regulatory approval for our product candidates.

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

We may not be able to initiate or continue clinical trials for 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 institutional review board, or similar regulatory authorities outside the United States, may also require that we suspend, discontinue, or limit our clinical trials based on safety information. Such findings could further result in regulatory

authorities failing to provide marketing authorization for our product candidates. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

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

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

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

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

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

To date, we have completed two Phase 2 studies in plaque psoriasis and a Phase 2 proof of concept study in atopic dermatitis with roflumilast cream, and have initiated a Phase 3 program in plaque psoriasis, which includes three studies comprised of two pivotal studies (DERMIS-1 and DERMIS-2) and an open label extension. We also anticipate commencing more advanced clinical trials of roflumilast cream in the treatment of atopic dermatitis. Failure to successfully complete, or delays in, our pivotal trials or related regulatory submissions would prevent us from or delay us in obtaining regulatory approval for our product candidates. In addition, it is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our applications that they are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept our applications or issue marketing authorizations for our product candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA for any other applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Additionally, similar risks could apply to receipt of marketing authorizations by comparable regulatory authorities in foreign jurisdictions.

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

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

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

- the safety, efficacy, risk-benefit profile and potential advantages compared to alternative or existing treatments, such as steroids topical treatments, oral treatments, and biologic injections for the treatment of psoriasis, which physicians may perceive to be adequately effective for some or all patients;
- side effects that may be attributable to our product candidates and the difficulty of or costs associated with resolving such side effects;
- limitations or warnings contained in the labeling approved for our product candidates by FDA or other applicable foreign regulatory authorities;
- any restrictions on the use of our products, and the prevalence and severity of any side effects;
- the content of the approved product label;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments and over-the-counter, or OTC treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies over existing therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement at any given price level of each of our product candidates;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of any of our product candidates.

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

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

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

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

As to any of our product candidates that become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new

product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our prescription-only products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

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

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

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

Our current sales and marketing organization consists of two employees, our Chief Commercial Officer and our Vice President of Marketing. 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 do not currently have any infrastructure for the sales, marketing, or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

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

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

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, 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., 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., 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 ruxolitinib, under development by Incyte Corporation, 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 Dermira, Inc.

For hand eczema, our primary competitors include topical therapies such as branded and generic versions of clobetasol, such as Clobex, and generic versions of betamethasone dipropionate. The only other prescription product candidate we are aware of under development for the treatment of hand eczema that would compete with ARQ-252 is delgocitinib, 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 March 31, 2020, we had 43 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our lead product candidates or any future product candidates.

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

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

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

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

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

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

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

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

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

We may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. We will face, to the extent that we decide to enter into

collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us. Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with 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 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 Medical Officer, Howard G. Welgus, M.D., and our Chief Technical Officer, David W. Osborne, Ph.D. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our products or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

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

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

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

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

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

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;

- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future product candidates we develop. Although we currently carry product liability insurance covering our clinical trials, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

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

We completed our IPO in January 2020 and are subject to public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, We will incur significant legal, accounting and other expenses as a public company, including costs resulting from such public company reporting obligations and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with our next annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, or a "smaller reporting company" (SRC) and non-accelerated filer, 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. Once we are no longer an emerging growth company and otherwise do not meet the definition of a SRC and non-accelerated filer or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. We could qualify as a SRC if the market value of our common stock held by non-affiliates is below $250 million (or $700 million if our annual revenue is less than $100 million) as of June 30 in any given year.

In addition, we expect that we will need to implement an enterprise resource planning, or ERP, system for our company. An ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. However, an ERP system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Additionally, during the conversion process, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in implementing or using an ERP system could adversely affect our controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. For example outbreaks of epidemic, pandemic, or contagious diseases, such as the recent 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 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.

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.

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 the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. By way of example, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes 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 similar laws have been proposed at the federal level and in other states as well as in non-U.S. jurisdictions. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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

We are exposed to the risk that our future commercial partners, as well as our employees and independent contractors, including principal investigators, consultants, suppliers, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such foreign regulatory authorities; manufacturing standards; U.S. federal and state healthcare fraud

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

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Risks Related to Our Reliance on Third Parties

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

We do not currently have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. Instead, we currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. In the fourth quarter of 2019, we received a batch of our product candidate that we believe is representative of our anticipated early commercial batch requirements. 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 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. Additionally, we have not yet engaged any manufacturer for the commercial supply of our product candidates. Although we intend to enter into such agreements prior to commercial launch of any of our product candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial manufacture of our product candidates, we will have no other means of producing our lead product candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturer's facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

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

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

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

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

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

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

If a third-party manufacturer with whom we contract is unable to comply with applicable laws and regulations, including cGMPs, 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 good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that appropriate human subjects protections are in place, including that the trial subjects are adequately informed of the potential risks and other consequences of participating in clinical trials.

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

Risks Related to Intellectual Property

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

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

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

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current licensors, or any future licensors or licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made

in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted, and as a result may not be able to be enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how to our processes, methods, and know-how which we consider our trade secrets. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

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

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any, over such aspects of our technology. Even if patents do successfully issue covering such aspects of our technology, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we own or license 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 are currently projected to expire on June 7, 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 patent term extension is granted. Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of 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 United States Patent and Trademark Office, or the USPTO, to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

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

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

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

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

The validity, scope and enforceability of any patents listed in the Orange Book that cover 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 new drug application, 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, are currently projected to expire on June 7, 2037. Certain issued U.S. patents that we have licensed from Hengrui relating to, among other things, treatment of several diseases or disorders, including various cancers, allograft rejection, graft versus host disease, rheumatoid arthritis, atopic dermatitis, and psoriasis with SHR0302, or bisulfate and crystal forms thereof, are currently projected to expire beginning in 2033. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

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

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

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

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

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

Additional third parties, apart from our current licensors, may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of these third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms, in which case our business would be harmed. The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could harm our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

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

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

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

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

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

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

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

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

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

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

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

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

We have not yet registered trademarks for a commercial trade name for our lead product candidates in the United States or any foreign jurisdiction. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are

given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

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

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

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

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

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

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

of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

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

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

Our commercial success depends in part on our and our licensors avoiding infringement and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

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

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

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely impact our ability to raise additional funds or otherwise harm our business, results of operation, financial condition or cash flows.

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

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

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

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

Risks Related to Government Regulation

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

Any regulatory approvals or other marketing authorizations we obtain for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or the conditions of approval or marketing authorization, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our drug product candidates, such as roflumilast cream, roflumilast foam, ARQ-252 and ARQ-255, which could include requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority authorizes our product candidates for marketing, the

manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

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

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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

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

the FDA or another governmental authority, if such products are marketed, could have a negative impact on us.

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

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business

associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, (as well as certain other healthcare professionals beginning in 2022) and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members;
- state privacy laws and regulations, such as those of California, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information (for example, in June 2018, California enacted the California Consumer Privacy Act (which will go into effect on January 1, 2020) that gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, and provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation; resulting in increased compliance costs and potential liability);
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States, including in Canada and Europe. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory authorities have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

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

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

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include the Budget Control Act of 2011, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year and will remain in effect through 2029; the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years; and the Medicare Access and CHIP Reauthorization Act of 2015, which, among other things, ended the use of the sustainable growth rate formula and provides for a 0.5% update to physician payment rates for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products.

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

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

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

The FDA and other foreign regulatory authorities strictly regulate the marketing of and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other foreign regulatory authorities as reflected in the product's approved labeling. In addition, although we believe our product candidates may exhibit a lower risk of side effects or more favorable tolerability profile or better symptomatic improvement than other products for the indications we are studying, without head-to-head data, we will be unable to make comparative claims for our product candidates, if approved. If we receive regulatory approval for any of our products and are found to have promoted any of our products for off-label uses, we may become subject to significant liability, which would materially harm our business. Both federal

and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our brand and reputation could be damaged. The FDA has also previously requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they determine our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

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

Risks Related to Our Common Stock

The stock price of our common stock may be volatile or may decline and investors may not be able to resell their shares at or above the IPO price.

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

- limited daily trading volume resulting in the lack of a liquid market;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- regulatory, 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 Quarterly Report on Form 10-Q.

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.

An active, liquid and orderly market for our common stock may not develop.

Prior to our IPO, there had been no public market for shares of our common stock, and an active public market for our shares may not develop or be sustained. The lack of an active market may impair the ability to sell our shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

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.

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

We qualify as an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including certain reduced financial statement reporting obligations, reduced disclosure obligations about our executive compensation arrangements, exemptions from the requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements and exemption from the auditor's attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of the IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

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

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

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

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

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

As of March 31, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 48% of our voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position, including the ability to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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 24.4 million shares of our common stock 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, or NOL, carryforwards and research and development income tax credit carryforwards may be limited.

As of December 31, 2019, we had NOL carryforwards available to reduce future taxable income, if any, for federal and California income tax purposes of $54.6 million and $55.1 million, respectively. If not utilized, California NOL carryforwards will expire beginning in 2036. Of the federal net operating losses, $3.5 million originated before the 2019 tax year and will expire beginning in 2036. Under the Tax Act, the remaining $51.0 million of federal NOL carryforwards generated after December 31, 2017 will carryforward indefinitely with utilization limited to 80% of taxable income. As of December 31, 2019, we had federal and California research and development tax credit carryforwards of $2.0 million and $0.7 million, respectively. If not utilized, the federal research and development tax credit carryforwards will begin to expire in 2037. The California research and development tax credit carryforwards are available indefinitely.

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership by certain stockholders over a three year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. A formal study has not been completed to determine if a change in ownership, as defined by Section 382, has occurred. We believe that we may undergo an “ownership change” limitation as a result of 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.

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

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

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

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

- The rights conferred in our restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our restated certificate of incorporation 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, or the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

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

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

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

From January 1, 2020 through March 31, 2020, we sold and issued the following unregistered securities:

1. We sold an aggregate of 43,000 shares of common stock to employees and consultants for cash consideration in the aggregate amount of $145,000 upon the exercise of stock options.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering, and the Registrant believes each transaction was exempt from the registration requirements of the Securities Act as stated above.

Use of Proceeds

On January 30, 2020, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-235806), as amended, filed in connection with our IPO. 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

We did not repurchase any of our equity securities during the three months ended March 31, 2020.

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 Herewith
3.1	Restated Certificate of Incorporation.				X
3.2	Restated Bylaws.				X
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#	Form of Indemnity Agreement.	S-1	1/6/20	10.1	
10.2#	2017 Stock Incentive Plan and forms of award agreements.	S-1	1/6/20	10.2	
10.3#	2020 Stock Incentive Plan and forms of award agreements.	S-1/A	1/21/20	10.3	
10.4#	2020 Employee Stock Purchase Plan and forms of award agreements.	S-1/A	1/21/20	10.4	

10.5#	Offer Letter, dated January 9, 2020, by and between the Registrant and Todd Franklin Watanabe.	S-1/A	1/21/20	10.5	
10.6#	Offer Letter, dated January 9, 2020, by and between the Registrant and David W. Osborne.	S-1/A	1/21/20	10.6	
10.7#	Offer Letter, dated January 9, 2020, by and between the Registrant and Howard G. Welgus, M.D.	S-1/A	1/21/20	10.7	
10.8#	Offer Letter, dated January 9, 2020, by and between the Registrant and John W. Smither.	S-1/A	1/21/20	10.8	
10.9#	Offer Letter, dated January 9, 2020, by and between the Registrant and Kenneth A. Lock.	S-1/A	1/21/20	10.9	
10.10#	Offer Letter, dated January 9, 2020, by and between the Registrant and Patricia A. Turney.	S-1/A	1/21/20	10.10	
10.11#	Consulting Agreement, dated August 16, 2016, by and between Bhaskar Chaudhuri and the Registrant.	S-1	1/6/20	10.11	
10.12†^	License Agreement, dated July 23, 2018, by and between AstraZeneca AB and the Registrant.	S-1	1/6/20	10.12	
10.13†^	Exclusive Option and License Agreement, dated January 4, 2018, by and between Jiangsu Hengrui Medicine Co., Ltd. and the Registrant.	S-1	1/6/20	10.13	
10.14†^	Collaboration Agreement, dated June 28, 2019, by and between Hawkeye Therapeutics, Inc. and the Registrant.	S-1	1/6/20	10.14	
10.15#	Transition and Amendment Agreement, dated December 13, 2019 by and between Bhaskar Chaudhuri and the Registrant.	S-1	1/6/20	10.15	
10.16	Option Notice and Amendment No. 2 to Exclusive Option and License Agreement, dated December 5, 2019, by and between Jiangsu Hengrui Medicine Co., Ltd. and the Registrant.	S-1	1/6/20	10.16	
10.17#	Severance & Change in Control Agreement, by and between the Registrant and Todd Franklin Watanabe.	S-1/A	1/21/20	10.17	
10.18#	Severance & Change in Control Agreement, by and between the Registrant and David W. Osborne.	S-1/A	1/21/20	10.18	
10.19#	Severance & Change in Control Agreement, by and between the Registrant and Howard G. Welgus, M.D.	S-1/A	1/21/20	10.19	
10.20#	Severance & Change in Control Agreement, by and between the Registrant and John W. Smither.	S-1/A	1/21/20	10.20	
10.21#	Severance & Change in Control Agreement, by and between the Registrant and Kenneth A. Lock.	S-1/A	1/21/20	10.21	
10.22#	Severance & Change in Control Agreement, by and between the Registrant and Patricia A. Turney.	S-1/A	1/21/20	10.22	
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	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	XBRL Taxonomy Extension Schema Document.				X

101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	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.

^ Registrant has omitted schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission 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: May 12, 2020

By: /s/ John W. Smither

John W. Smither
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 3.1

ARCUTIS BIOTHERAPEUTICS, INC.

RESTATED CERTIFICATE OF INCORPORATION

Arcutis Biotherapeutics, Inc., a Delaware corporation, hereby certifies as follows:

1. The name of the corporation is Arcutis Biotherapeutics, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State was June 1, 2016 under the name Arcutis, Inc.

2. The Restated Certificate of Incorporation of the corporation attached hereto as Exhibit A, which is incorporated herein by this reference, and which restates, integrates and further amends the provisions of the Certificate of Incorporation of this corporation as previously amended and/or restated, has been duly adopted by this corporation's Board of Directors and by the stockholders in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, with the approval of the corporation's stockholders having been given by written consent without a meeting in accordance with Section 228 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, this corporation has caused this Restated Certificate of Incorporation to be signed by its duly authorized officer and the foregoing facts stated herein are true and correct.

Dated: February 4, 2020

ARCUTIS BIOTHERAPEUTICS, INC.

By: **/s/ Todd Franklin Watanabe**

Name: Todd Franklin Watanabe

Title: Chief Executive Officer

ARCUTIS BIOTHERAPEUTICS, INC.

RESTATED CERTIFICATE OF INCORPORATION

ARTICLE I: NAME

The name of the corporation is Arcutis Biotherapeutics, Inc. (collectively with its subsidiaries, the "***Corporation***").

ARTICLE II: AGENT FOR SERVICE OF PROCESS

The address of the Corporation's registered office in the State of Delaware is 3500 South Dupont Highway, in the City of Dover, County of Kent 19901. The name of the registered agent of the Corporation at that address is Incorporating Services, Ltd.

ARTICLE III: PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "***General Corporation Law***").

ARTICLE IV: AUTHORIZED STOCK

1. Total Authorized. The total number of shares of all classes of stock that the Corporation has authority to issue is Three Hundred Ten Million (310,000,000) shares, consisting of two classes: Three Hundred Million (300,000,000) shares of Common Stock, $0.0001 par value per share ("***Common Stock***"), and Ten Million (10,000,000) shares of Preferred Stock, $0.0001 par value per share ("***Preferred Stock***").

2. Designation of Additional Series.

2.1. The Board of Directors of the Corporation (the "***Board***") is authorized, subject to any limitations prescribed by the law of the State of Delaware, to provide for the issuance of the shares of Preferred Stock in one or more series, and, by filing a Certificate of Designation pursuant to the applicable law of the State of Delaware ("***Certificate of Designation***"), to establish from time to time the number of shares to be included in each such series, to fix the designation, vesting, powers (including voting powers), preferences and relative, participating, optional or other special rights, if any, of the shares of each such series and any qualifications, limitations or restrictions thereof, and, except where otherwise provided in the applicable Certificate of Designation, to thereafter increase (but not above the total number of authorized shares of the Preferred Stock) or decrease (but not below the number of shares of such series then outstanding) the number of shares of any such series. The number of authorized shares of Preferred Stock may also be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of two-thirds of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, without a separate vote of the holders of the Preferred Stock, unless a vote of any such holders is required pursuant to the terms of any certificate or certificates establishing a series of Preferred Stock.

2.2 Except as otherwise expressly provided in any Certificate of Designation designating any series of Preferred Stock pursuant to the foregoing provisions of this Article IV, any new series of Preferred Stock may be designated, fixed and determined as provided herein by the Board without approval of the holders of Common Stock or the holders of Preferred Stock, or any series thereof, and any such new series may have powers, preferences and rights, including, without limitation, voting rights, dividend rights, liquidation rights, redemption rights and

conversion rights, senior to, junior to or pari passu with the rights of the Common Stock, the Preferred Stock or any future class or series of Preferred Stock or Common Stock.

2.3 Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; *provided*, *however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Restated Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Restated Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock).

ARTICLE V: AMENDMENT OF BYLAWS

The Board shall have the power to adopt, amend or repeal the Bylaws of the Corporation (as the same may be amended and/or restated from time to time, the "***Bylaws***"). Any adoption, amendment or repeal of the Bylaws by the Board shall require the approval of a majority of the Whole Board. For purposes of this Restated Certificate of Incorporation, the term "***Whole Board***" shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships. The stockholders shall also have power to adopt, amend or repeal the Bylaws; *provided*, *however*, that notwithstanding any other provision of this Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser or no vote, but in addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Restated Certificate of Incorporation (including any Preferred Stock issued pursuant to a Certificate of Designation), the affirmative vote of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal any provision of the Bylaws; *provided further*, that, in the case of any proposed adoption, amendment or repeal of any provisions of the Bylaws that is approved by the Board and submitted to the stockholders for adoption thereby, if two-thirds of the Whole Board has approved such adoption, amendment or repeal of any provisions of the Bylaws, then only the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws.

ARTICLE VI: MATTERS RELATING TO THE BOARD OF DIRECTORS

1. Director Powers. Except as otherwise provided by the General Corporation Law, the conduct of the affairs of the Corporation shall be managed by or under the direction of the Board. In addition to the powers and authority expressly conferred upon them by applicable law or by this Restated Certificate of Incorporation or the Bylaws of the Corporation, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.

2. Number of Directors. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the total number of directors constituting the Whole Board shall be fixed from time to time exclusively by resolution adopted by a majority of the Whole Board.

3. Classified Board. Subject to the special rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided, with respect to the time for which they severally hold office, into three classes designated as Class I, Class II and Class III, respectively (the "***Classified Board***"). The Board may assign members of the Board already in office to the Classified Board, which assignments shall become effective at the same time the Classified Board becomes effective. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board. The number of directors in each class shall be divided as nearly equal as reasonably possible. The initial term of office of the Class I directors

shall expire at the Corporation's first annual meeting of stockholders following the closing of the Corporation's initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, relating to the offer and sale of Common Stock to the public (the "***Initial Public Offering***"), the initial term of office of the Class II directors shall expire at the Corporation's second annual meeting of stockholders following the closing of the Initial Public Offering and the initial term of office of the Class III directors shall expire at the Corporation's third annual meeting of stockholders following the closing of the Initial Public Offering. At each annual meeting of stockholders following the closing of the Initial Public Offering, directors elected to succeed those directors of the class whose terms then expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election.

4. **Term and Removal**. Each director shall hold office until the annual meeting at which such director's term expires and until such director's successor is duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal. Any director may resign at any time upon notice to the Corporation given in writing or by any electronic transmission permitted in the Bylaws. Subject to the special rights of the holders of any series of Preferred Stock, no director may be removed from the Board except for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of the then-outstanding shares of capital stock of the Corporation entitled to vote at an election of directors, voting together as a single class. No decrease in the authorized number of directors constituting the Whole Board shall shorten the term of any incumbent director.

5. **Board Vacancies and Newly Created Directorships**. Subject to the special rights of the holders of any series of Preferred Stock, any vacancy occurring in the Board for any cause, and any newly created directorship resulting from any increase in the authorized number of directors, shall, unless (a) the Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders or (b) as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even if less than a quorum, or by a sole remaining director, and shall not be filled by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for a term expiring at the annual meeting of stockholders at which the term of office of the class to which the director has been assigned expires or until such director's successor shall have been duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal.

6. **Vote by Ballot**. Election of directors need not be by written ballot unless the Bylaws shall so provide.

ARTICLE VII: DIRECTOR LIABILITY

1. **Limitation of Liability**. To the fullest extent permitted by law, no director of the Corporation shall be personally liable for monetary damages for breach of fiduciary duty as a director. Without limiting the effect of the preceding sentence, if the General Corporation Law is hereafter amended to authorize the further elimination or limitation of the liability of a director, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law, as so amended.

2. **Change in Rights**. Neither any amendment nor repeal of this Article VII, nor the adoption of any provision of this Restated Certificate of Incorporation inconsistent with this Article VII, shall eliminate, reduce or otherwise adversely affect any limitation on the personal liability of a director of the Corporation existing at the time of such amendment, repeal or adoption of such an inconsistent provision.

ARTICLE VIII: MATTERS RELATING TO STOCKHOLDERS

1. **No Action by Written Consent of Stockholders**. Subject to the rights of any series of Preferred Stock then outstanding, no action shall be taken by the stockholders of the Corporation except at a duly called annual or special meeting of stockholders and no action shall be taken by the stockholders of the Corporation by written consent.

2. **Special Meeting of Stockholders**. Special meetings of the stockholders of the Corporation may be called only by the Chairperson of the Board, the Chief Executive Officer, the President, or the Board acting pursuant to a resolution adopted by a majority of the Whole Board and may not be called by any other person or persons.

3. **Advance Notice of Stockholder Nominations and Business Transacted at Special Meetings**. Advance notice of stockholder nominations for the election of directors of the Corporation and of business to be brought by stockholders before any meeting of stockholders of the Corporation shall be given in the manner provided in the Bylaws. Business transacted at special meetings of stockholders shall be limited to the purpose or purposes stated in the notice of meeting.

ARTICLE IX: CHOICE OF FORUM

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware, to the fullest extent permitted by law, shall be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of the Corporation; (b) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any director, officer, stockholder, employee or agent of the Corporation to the Corporation or the Corporation's stockholders; (c) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation arising pursuant to any provision of the General Corporation Law, this Restated Certificate of Incorporation or the Bylaws; (d) any action to interpret, apply, enforce or determine the validity of this Restated Certificate of Incorporation or the Bylaws; or (e) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation governed by the internal affairs doctrine.

Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and to have consented to the provisions of this Article IX.

ARTICLE X: AMENDMENT OF CERTIFICATE OF INCORPORATION

If any provision of this Restated Certificate of Incorporation becomes or is declared on any ground by a court of competent jurisdiction to be illegal, unenforceable or void, portions of such provision, or such provision in its entirety, to the extent necessary, shall be severed from this Restated Certificate of Incorporation, and the court will replace such illegal, void or unenforceable provision of this Restated Certificate of Incorporation with a valid and enforceable provision that most accurately reflects the Corporation's intent, in order to achieve, to the maximum extent possible, the same economic, business and other purposes of the illegal, void or unenforceable provision. The balance of this Restated Certificate of Incorporation shall be enforceable in accordance with its terms.

The Corporation reserves the right to amend or repeal any provision contained in this Restated Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; *provided*, *however*, that, notwithstanding any other provision of this Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote, but in addition to any vote of the holders of any class or series of the stock of the Corporation required by law or by this Restated Certificate of Incorporation, the affirmative vote of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend or repeal this Article X or Article V, Article VI, Article VII or Article VIII; *provided*, *further*, that if two-thirds of the Whole Board has approved such amendment or repeal of any provisions of this Restated Certificate of Incorporation, then only the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend or repeal such provisions of this Restated Certificate of Incorporation.

Exhibit 3.2

ARCUTIS BIOTHERAPEUTICS, INC.

(a Delaware corporation)

RESTATED BYLAWS

February 4, 2020

ARCUTIS BIOTHERAPEUTICS, INC.

(a Delaware corporation)

RESTATED BYLAWS

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ARCUTIS BIOTHERAPEUTICS, INC.

(a Delaware corporation)

RESTATED BYLAWS

February 4, 2020

ARTICLE I: STOCKHOLDERS

Section 1.1: Annual Meetings

An annual meeting of stockholders shall be held for the election of directors at such date and time as the Board of Directors (the "***Board***") of Arcutis Biotherapeutics, Inc. (collectively with its subsidiaries, the "***Corporation***") shall each year fix. The meeting may be held either at a place, within or without the State of Delaware as permitted by the Delaware General Corporation Law (the "***DGCL***"), or by means of remote communication as the Board in its sole discretion may determine. Any proper business may be transacted at the annual meeting.

Section 1.2: Special Meetings

Special meetings of stockholders for any purpose or purposes may be called at any time by the Chairperson of the Board, the Chief Executive Officer, the President or the Board acting pursuant to a resolution adopted by a majority of the Whole Board (as defined below). Special meetings may not be called by any other person or persons. The special meeting may be held either at a place, within or without the State of Delaware, or by means of remote communication as the Board in its sole discretion may determine. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of the meeting.

Section 1.3: Notice of Meetings

Notice of all meetings of stockholders shall be given in writing or by electronic transmission in the manner provided by applicable law (including, without limitation, as set forth in Section 7.1.1 of these Bylaws) stating the date, time and place, if any, of the meeting and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. In the case of a special meeting, such notice shall also set forth the purpose or purposes for which the meeting is called. Unless otherwise required by applicable law or the Restated Certificate of Incorporation of the Corporation (as the same may be amended and/or restated from time to time, the "***Certificate of Incorporation***"), notice of any meeting of stockholders shall be given not less than ten (10), nor more than sixty (60), days before the date of the meeting to each stockholder of record entitled to vote at such meeting.

Section 1.4: Adjournments

The chairperson of the meeting shall have the power to adjourn the meeting to another time, date and place (if any). Any meeting of stockholders may be adjourned from time to time, and notice need not be given of any such adjourned meeting if the time, date and place (if any) thereof and the means of remote communication (if any) by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; *provided*, *however*, that if the adjournment is for more than thirty (30) days, or if a new record date is fixed for the adjourned meeting, then a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. At the adjourned meeting, the Corporation may transact any business that might have been transacted at the original meeting. To the fullest extent permitted by law, the Board may postpone, reschedule or cancel any previously scheduled special or annual meeting of stockholders before it is to be held, in which case notice shall be provided to the stockholders of the new date, time and place, if any, of the meeting as provided in Section 1.3 above.

Section 1.5: Quorum

At each meeting of stockholders the holders of a majority of the voting power of the shares of stock entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business, unless otherwise required by applicable law. Where a separate vote by a class or classes or series is required, a majority of the voting power of the shares of such class or classes or series present in person or represented by proxy shall constitute a quorum entitled to take action with respect to that vote on that matter. If a quorum shall fail to attend any meeting, the chairperson of the meeting or the holders of a majority of the shares entitled to vote who are present, in person or by proxy, at the meeting may adjourn the meeting. Shares of the Corporation's stock belonging to the Corporation (or to another corporation, if a majority of the shares entitled to vote in the election of directors of such other corporation are held, directly or indirectly, by the Corporation), shall neither be entitled to vote nor be counted for quorum purposes; *provided*, *however*, that the foregoing shall not limit the right of the Corporation or any other corporation to vote any shares of the Corporation's stock held by it in a fiduciary capacity and to count such shares for purposes of determining a quorum.

Section 1.6: Organization

Meetings of stockholders shall be presided over by (a) such person as the Board may designate, or (b) in the absence of such a person, the Chairperson of the Board, or (c) in the absence of such person, the Chief Executive Officer of the Corporation, or (d) in the absence of such person, the President of the Corporation, or (e) in the absence of such person, such person as may be chosen by the holders of a majority of the voting power of the shares entitled to vote who are present, in person or by proxy, at the meeting. Such person shall be chairperson of the meeting and, subject to Section 1.10 hereof, shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of discussion as seems to him or her to be in order. The Secretary of the Corporation shall act as secretary of the meeting, but in such person's absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 1.7: Voting; Proxies

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy. Such a proxy may be prepared, transmitted and delivered in any manner permitted by applicable law. Except as may be required in the Certificate of Incorporation, directors shall be elected by a plurality of the votes cast. Unless otherwise provided by applicable law, the rules of any stock exchange upon which the Corporation's securities are listed, the Certificate of Incorporation or these Bylaws, every matter other than the election of directors shall be decided by a majority of the votes cast for or against the matter.

Section 1.8: Fixing Date for Determination of Stockholders of Record

In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, unless otherwise required by law, the Board may fix, in advance, a record date, which shall not precede the date upon which the resolution fixing the record date is adopted by the Board and which shall not be more than sixty (60), nor less than ten (10), days before the date of such meeting, nor more than sixty (60) days prior to any other action. If no record date is fixed by the Board, then the record date shall be as provided by applicable law. To the fullest extent permitted by law, a determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided*, *however*, that the Board may fix a new record date for the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix, in advance, a record date, which shall not precede the date upon which the resolution fixing the record date is adopted by the Board and which shall not be more than sixty (60) days prior to such action. If no such record date is fixed by the Board, then the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

Section 1.9: List of Stockholders Entitled to Vote

A complete list of stockholders entitled to vote at any meeting of stockholders, arranged in alphabetical order and showing the address of each stockholder and the number of shares registered in the name of each stockholder, shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either on a reasonably accessible electronic network as permitted by law (provided that the information required to gain access to the list is provided with the notice of the meeting) or during ordinary business hours at the principal place of business of the Corporation. If the meeting is held at a location where stockholders may attend in person, the list shall also be produced and kept at the time and place of the meeting during the whole time thereof and may be inspected by any stockholder who is present at the meeting. If the meeting is held solely by means of remote communication, then the list shall be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access the list shall be provided with the notice of the meeting.

Section 1.10: Inspectors of Elections

1.10.1 Applicability. Unless otherwise required by the Certificate of Incorporation or by the DGCL, the following provisions of this Section 1.10 shall apply only if and when the Corporation has a class of voting stock that is: (a) listed on a national securities exchange; (b) authorized for quotation on an interdealer quotation system of a registered national securities association; or (c) held of record by more than two thousand (2,000) stockholders. In all other cases, observance of the provisions of this Section 1.10 shall be optional, and at the discretion of the Board.

1.10.2 Appointment. The Corporation shall, in advance of any meeting of stockholders, appoint one or more inspectors of election to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting.

1.10.3 Inspector's Oath. Each inspector of election, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability.

1.10.4 Duties of Inspectors. At a meeting of stockholders, the inspectors of election shall (a) ascertain the number of shares outstanding and the voting power of each share, (b) determine the shares represented at a meeting and the validity of proxies and ballots, (c) count all votes and ballots, (d) determine and retain for a reasonable period of time a record of the disposition of any challenges made to any determination by the inspectors, and (e) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

1.10.5 Opening and Closing of Polls. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting. No ballot, proxies or votes, nor any revocations thereof or changes thereto, shall be accepted by the inspectors after the closing of the polls unless the Court of Chancery upon application by a stockholder shall determine otherwise.

1.10.6 Determinations. In determining the validity and counting of proxies and ballots, the inspectors shall be limited to an examination of the proxies, any envelopes submitted with those proxies, any information provided in connection with proxies pursuant to Section 211(a)(2)(b)(i) or (iii) of the DGCL, or in accordance with Sections 211(e) or 212(c)(2) of the DGCL, ballots and the regular books and records of the Corporation, except that the inspectors may consider other reliable information for the limited purpose of reconciling proxies and ballots submitted by or on behalf of banks, brokers, their nominees or similar persons which represent more votes than the holder of a proxy is authorized by the record owner to cast or more votes than the stockholder holds of record. If the inspectors consider other reliable information for the limited purpose permitted herein, the inspectors at the time they make their certification of their determinations pursuant to this Section 1.10 shall specify the precise information considered by them, including the person or persons from whom they obtained the information, when

the information was obtained, the means by which the information was obtained and the basis for the inspectors' belief that such information is accurate and reliable.

Section 1.11: Notice of Stockholder Business; Nominations.

1.11.1 Annual Meeting of Stockholders.

(a) Nominations of persons for election to the Board and the proposal of business to be considered by the stockholders shall be made at an annual meeting of stockholders (i) pursuant to the Corporation's notice of such meeting, (ii) by or at the direction of the Board or (iii) by any stockholder of the Corporation who was a stockholder of record at the time of giving of the notice provided for in this Section 1.11, who is entitled to vote at such meeting and who complies with the notice procedures set forth in this Section 1.11. For the avoidance of doubt, the foregoing clause (iii) shall be the exclusive means for a stockholder to make nominations or propose business (other than business included in the Corporation's proxy materials pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended (such act, and the rules and regulations promulgated thereunder, the "***Exchange Act***")), at an annual meeting of stockholders.

(b) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to Section 1.11.1(a):

(i) the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation;

(ii) such other business must otherwise be a proper matter for stockholder action;

(iii) if the stockholder, or the beneficial owner on whose behalf any such proposal or nomination is made, has provided the Corporation with a Solicitation Notice, as that term is defined in this Section, such stockholder or beneficial owner must, in the case of a proposal, have delivered a proxy statement and form of proxy to holders of at least the percentage of the Corporation's voting shares required under applicable law to carry any such proposal, or, in the case of a nomination or nominations, have delivered a proxy statement and form of proxy to holders of a percentage of the Corporation's voting shares reasonably believed by such stockholder or beneficial holder to be sufficient to elect the nominee or nominees proposed to be nominated by such stockholder, and must, in either case, have included in such materials the Solicitation Notice; and

(iv) if no Solicitation Notice relating thereto has been timely provided pursuant to this Section, the stockholder or beneficial owner proposing such business or nomination must not have solicited a number of proxies sufficient to have required the delivery of such a Solicitation Notice under this Section.

To be timely, a stockholder's notice must be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the seventy-fifth (75th) day nor earlier than the close of business on the one hundred and fifth (105th) day prior to the first anniversary of the preceding year's annual meeting (except in the case of the Corporation's first annual meeting following its initial public offering, for which such notice shall be timely if delivered in the same time period as if such meeting were a special meeting governed by Section 1.11.2); *provided*, *however*, that in the event that the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, notice by the stockholder to be timely must be so delivered (A) no earlier than the close of business on the one hundred and fifth (105th) day prior to currently proposed annual meeting and (B) no later than the close of business on the later of the seventy-fifth (75th) day prior to such annual meeting or the close of business on the tenth (10th) day following the day on which Public Announcement of the date of such meeting is first made by the Corporation. Such stockholder's notice shall set forth:

(x) as to each person whom the stockholder proposes to nominate for election or reelection as a director all information relating to such person that would be required to be disclosed in solicitations of proxies for election of directors, or would be otherwise required, in each case pursuant to Regulation 14A under the Exchange Act, including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected;

(y) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made; and

(z) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made, (aa) the name and address of such stockholder, as they appear on the Corporation's books, and of such beneficial owner, (bb) the class and number of shares of the Corporation that are owned beneficially and held of record by such stockholder and such beneficial owner, (cc) a description of any agreement, arrangement or understanding with respect to the nomination or proposal between or among such stockholder and such beneficial owner, any of their respective affiliates or associates, and any others acting in concert with any of the foregoing, (dd) a description of any agreement, arrangement or understanding (including any derivative or short positions, profit interests, options, warrants, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder and such beneficial owners, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner, with respect to shares of stock of the Corporation, (ee) a representation that the stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business or nomination and (ff) whether either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of the Corporation's voting shares required under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of the Corporation's voting shares to elect such nominee or nominees (an affirmative statement of such intent being a "***Solicitation Notice***"). If requested by the Corporation, the information required under clauses (bb), (cc) and (dd) of this subparagraph (z) shall be supplemented by such stockholder and beneficial owner, if any, not later than 10 days after the record date for the meeting to disclose such information as of the record date.

(c) Notwithstanding anything in the second sentence of Section 1.11.1(b) to the contrary, in the event that the number of directors to be elected to the Board is increased and there is no Public Announcement by the Corporation naming all of the nominees for director or specifying the size of the increased Board at least seventy five (75) days prior to the first anniversary of the preceding year's annual meeting (or, if the annual meeting is held more than thirty (30) days before or sixty (60) days after such anniversary date, at least seventy five (75) days prior to such annual meeting), a stockholder's notice required by this Section 1.11 shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary of the Corporation at the principal executive office of the Corporation no later than the close of business on the tenth (10th) day following the day on which such Public Announcement is first made by the Corporation.

1.11.2 Special Meetings of Stockholders. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of such meeting. Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of such meeting (a) by or at the direction of the Board or (b) provided that the Board has determined that directors shall be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time of giving of notice of the special meeting, who shall be entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 1.11. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board, any such stockholder may nominate a person or persons (as the case may be), for election to such position(s) as specified in the Corporation's notice of meeting, if the stockholder's notice required by Section 1.11.1(b) shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation (i) no earlier than the one hundred fifth (105th) day prior to such special meeting and (ii) no later than the close of business on the later of the seventy fifth (75th) day prior to such special meeting or the tenth (10th) day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting.

1.11.3 General.

(a) Only such persons who are nominated in accordance with the procedures set forth in this Section 1.11 shall be eligible to serve as directors and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 1.11. Except as otherwise provided by law or these Bylaws, the chairperson of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 1.11 and, if any proposed nomination or business is not in compliance herewith, to declare that such defective proposal or nomination shall be disregarded.

(b) For purposes of this Section 1.11, the term "***Public Announcement***" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

(c) Notwithstanding the foregoing provisions of this Section 1.11, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth herein. Nothing in this Section 1.11 shall be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

ARTICLE II: BOARD OF DIRECTORS

Section 2.1: Number; Qualifications

The total number of authorized directors constituting the Board, whether or not there exist any vacancies in previously authorized directorships (the "***Whole Board***") shall be fixed from time to time in the manner set forth in the Certificate of Incorporation. No decrease in the authorized number of directors constituting the Whole Board shall shorten the term of any incumbent director. Directors need not be stockholders of the Corporation.

Section 2.2: Election; Resignation; Removal; Vacancies

The directors shall be divided, with respect to the time for which they severally hold office, into classes as provided in the Certificate of Incorporation, and vacancies occurring in the Board and any newly created directorships resulting from any increase in the authorized number of directors shall be filled, as provided in the Certificate of Incorporation.

Section 2.3: Regular Meetings

Regular meetings of the Board may be held at such places, within or without the State of Delaware, and at such times as the Board may from time to time determine. Notice of regular meetings need not be given if the date, times and places thereof are fixed by resolution of the Board.

Section 2.4: Special Meetings

Special meetings of the Board may be called by the Chairperson of the Board, the Chief Executive Officer, or a majority of the members of the Board then in office and may be held at any time, date or place, within or without the State of Delaware, as the person or persons calling the meeting shall fix. Notice of the time, date and place of such meeting shall be given, orally, in writing or by electronic transmission (including electronic mail), by the person or persons calling the meeting to all directors at least four (4) days before the meeting if the notice is mailed, or at least twenty-four (24) hours before the meeting if such notice is given by telephone, hand delivery, telegram, telex, mailgram, facsimile, electronic mail or other means of electronic transmission. Unless otherwise indicated in the notice, any and all business may be transacted at a special meeting.

Section 2.5: Remote Meetings Permitted

Members of the Board, or any committee of the Board, may participate in a meeting of the Board or such committee by means of conference telephone or other communications equipment by means of which all persons

participating in the meeting can hear each other, and participation in a meeting pursuant to conference telephone or other communications equipment shall constitute presence in person at such meeting.

Section 2.6: Quorum; Vote Required for Action

Subject to the Certificate of Incorporation regarding the ability of members of the Board to fill a vacancy occurring in the Board, a majority of the Whole Board shall constitute a quorum for the transaction of business. If a quorum shall fail to attend any meeting, a majority of those present may adjourn the meeting to another place, date or time with further notice thereof. Except as otherwise provided herein or in the Certificate of Incorporation, or required by law, the vote of a majority of the directors present at a meeting at which a quorum is present shall be the act of the Board.

Section 2.7: Organization

Meetings of the Board shall be presided over by (a) the Chairperson of the Board, or (b) in such person's absence, by the Chief Executive Officer, or (c) in such person's absence, by a chairperson chosen at the meeting. The Secretary shall act as secretary of the meeting, but in such person's absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 2.8: Written Action by Directors

Any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or such committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee, respectively, in the minute books of the Corporation. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 2.9: Powers

The Board may, except as otherwise required by law or the Certificate of Incorporation, exercise all such powers and manage and direct all such acts and things as may be exercised or done by the Corporation.

Section 2.10: Compensation of Directors

Members of the Board, as such, may receive, pursuant to a resolution of the Board, fees and other compensation for their services as directors, including without limitation their services as members of committees of the Board.

ARTICLE III: COMMITTEES

Section 3.1: Committees

The Board may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of the committee, the member or members thereof present at any meeting of such committee who are not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in place of any such absent or disqualified member. Any such committee, to the extent provided in a resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority in reference to the following matters: (a) approving, adopting, or recommending to the stockholders any action or matter (other than the election or removal of members of the Board) expressly required by the DGCL to be submitted to stockholders for approval or (b) adopting, amending or repealing any bylaw of the Corporation.

Section 3.2: Committee Rules

Each committee shall keep records of its proceedings and make such reports as the Board may from time to time request. Unless the Board otherwise provides, each committee designated by the Board may make, alter and repeal rules for the conduct of its business. In the absence of such rules, each committee shall conduct its business in the same manner as the Board conducts its business pursuant to Article II of these Bylaws. Except as otherwise provided in the Certificate of Incorporation, these Bylaws or the resolution of the Board designating the committee, any committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and may delegate to any such subcommittee any or all of the powers and authority of the committee.

ARTICLE IV: OFFICERS; CHAIRPERSON

Section 4.1: Generally

The officers of the Corporation shall consist of a Chief Executive Officer (who may be the Chairperson of the Board or the President), a President, a Secretary and a Treasurer and may consist of such other officers, including, without limitation, a Chief Financial Officer, and one or more Vice Presidents, as may from time to time be appointed by the Board. All officers shall be elected by the Board; *provided*, *however*, that the Board may empower the Chief Executive Officer of the Corporation to appoint any officer other than the Chief Executive Officer, the President, the Chief Financial Officer or the Treasurer. Except as otherwise provided by law, by the Certificate of Incorporation or these Bylaws, each officer shall hold office until such officer's successor is duly elected and qualified or until such officer's earlier resignation, death, disqualification or removal. Any number of offices may be held by the same person. Any officer may resign by delivering a resignation in writing or by electronic transmission to the Corporation at its principal office or to the Chairperson of the Board, the Chief Executive Officer, or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event. Any vacancy occurring in any office of the Corporation by death, resignation, removal or otherwise may be filled by the Board and the Board may, in its discretion, leave unfilled, for such period as it may determine, any offices.

Section 4.2: Chief Executive Officer

Subject to the control of the Board and such supervisory powers, if any, as may be given by the Board, the powers and duties of the Chief Executive Officer of the Corporation are:

(a) to act as the general manager and, subject to the control of the Board, to have general supervision, direction and control of the business and affairs of the Corporation;

(b) subject to Article I, Section 1.6 of these Bylaws, to preside at all meetings of the stockholders;

(c) subject to Article I, Section 1.2 of these Bylaws, to call special meetings of the stockholders to be held at such times and, subject to the limitations prescribed by law or by these Bylaws, at such places as he or she shall deem proper;

(d) to affix the signature of the Corporation to all deeds, conveyances, mortgages, guarantees, leases, obligations, bonds, certificates and other papers and instruments in writing which have been authorized by the Board or which, in the judgment of the Chief Executive Officer, should be executed on behalf of the Corporation; to sign certificates for shares of stock of the Corporation (if any); and, subject to the direction of the Board, to have general charge of the property of the Corporation and to supervise and control all officers, agents and employees of the Corporation; and

(e) to vote and otherwise act on, or to authorize any officer to vote or otherwise act on, on behalf of the Corporation, in person or by proxy, at any meeting of stockholders of or with respect to any action of stockholders of any other corporation in which this Corporation may hold securities and otherwise to exercise, or authorize any officer otherwise to exercise, any and all rights and powers which this Corporation may possess by reason of its ownership of securities in such other corporation.

The person holding the office of President shall be the Chief Executive Officer of the Corporation unless the Board shall designate another officer to be the Chief Executive Officer. If there is no President, and the Board has not designated any other officer to be the Chief Executive Officer, then the Chairperson of the Board shall be the Chief Executive Officer.

Section 4.3: Chairperson of the Board

Subject to the provisions of Section 2.7 of these Bylaws, the Chairperson of the Board shall have the power to preside at all meetings of the Board and shall have such other powers and duties as provided in these Bylaws and as the Board may from time to time prescribe.

Section 4.4: President

The person holding the office of Chief Executive Officer shall be the President of the Corporation unless the Board shall have designated one individual as the President and a different individual as the Chief Executive Officer of the Corporation. Subject to the provisions of these Bylaws and to the direction of the Board, and subject to the supervisory powers of the Chief Executive Officer (if the Chief Executive Officer is an officer other than the President), and subject to such supervisory powers and authority as may be given by the Board to the Chairperson of the Board, and/or to any other officer, the President shall have the responsibility for the general management and control of the business and affairs of the Corporation and the general supervision and direction of all of the officers, employees and agents of the Corporation (other than the Chief Executive Officer, if the Chief Executive Officer is an officer other than the President) and shall perform all duties and have all powers that are commonly incident to the office of President or that are delegated to the President by the Board.

Section 4.5: Chief Financial Officer

The person holding the office of Chief Financial Officer shall be the Treasurer of the Corporation unless the Board shall have designated another officer as the Treasurer of the Corporation. Subject to the direction of the Board and the Chief Executive Officer, the Chief Financial Officer shall perform all duties and have all powers that are commonly incident to the office of Chief Financial Officer.

Section 4.6: Treasurer

The person holding the office of Treasurer shall have custody of all monies and securities of the Corporation. The Treasurer shall make such disbursements of the funds of the Corporation as are authorized and shall render from time to time an account of all such transactions. The Treasurer shall also perform such other duties and have such other powers as are commonly incident to the office of Treasurer, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.7: Vice Presidents

Any Vice President shall perform such duties and possess such powers as the Board of Directors or the President may from time to time prescribe. In the event of the absence, inability or refusal to act of the President, the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the President and when so performing shall have at the powers of and be subject to all the restrictions upon the President. The Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.

Section 4.8: Secretary

The Secretary shall issue or cause to be issued all authorized notices for, and shall keep, or cause to be kept, minutes of all meetings of the stockholders and the Board. The Secretary shall have charge of the corporate minute books and similar records and shall perform such other duties and have such other powers as are commonly incident to the office of Secretary, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.9: Delegation of Authority

The Board may from time to time delegate the powers or duties of any officer of the Corporation to any other officers or agents of the Corporation, notwithstanding any provision hereof.

Section 4.10: Removal

Any officer of the Corporation shall serve at the pleasure of the Board and may be removed at any time, with or without cause, by the Board; *provided* that if the Board has empowered the Chief Executive Officer to appoint any officer of the Corporation, then such officer may also be removed by the Chief Executive Officer. Such removal shall be without prejudice to the contractual rights of such officer, if any, with the Corporation.

ARTICLE V: STOCK

Section 5.1: Certificates

The shares of capital stock of the Corporation shall be represented by certificates; provided, however, that the Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock may be uncertificated shares. Notwithstanding the adoption of such resolution by the Board, each holder of stock represented by certificates shall be entitled to have a certificate signed by or in the name of the Corporation by the Chairperson or Vice-Chairperson of the Board, or the President or a Vice President, and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary, of the Corporation, certifying the number of shares owned by such stockholder in the Corporation. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were an officer, transfer agent or registrar at the date of issue.

Section 5.2: Lost, Stolen or Destroyed Stock Certificates; Issuance of New Certificates or Uncertificated Shares

The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate previously issued by it, alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to agree to indemnify the Corporation and/or to give the Corporation a bond sufficient to indemnify it, against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate.

Section 5.3: Other Regulations

Subject to applicable law, the Certificate of Incorporation and these Bylaws, the issue, transfer, conversion and registration of shares represented by certificates and of uncertificated shares shall be governed by such other regulations as the Board may establish.

ARTICLE VI: INDEMNIFICATION

Section 6.1: Indemnification of Officers and Directors

Each person who was or is made a party to, or is threatened to be made a party to, or is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "***Proceeding***"), by reason of the fact that such person (or a person of whom such person is the legal representative), is or was a member of the Board or officer of the Corporation or a Reincorporated Predecessor (as defined below) or is or was serving at the request of the Corporation or a Reincorporated Predecessor as a member of the board of directors, officer or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to employee

benefit plans (for purposes of this Article VI, an "***Indemnitee***"), shall be indemnified and held harmless by the Corporation to the fullest extent permitted by the DGCL as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), against all expenses, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes and penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such Indemnitee in connection therewith, provided such Indemnitee acted in good faith and in a manner that the Indemnitee reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or Proceeding, had no reasonable cause to believe the Indemnitee's conduct was unlawful. Such indemnification shall continue as to an Indemnitee who has ceased to be a director or officer and shall inure to the benefit of such Indemnitees' heirs, executors and administrators. Notwithstanding the foregoing, the Corporation shall indemnify any such Indemnitee seeking indemnity in connection with a Proceeding (or part thereof) initiated by such Indemnitee only if such Proceeding (or part thereof) was authorized by the Board or such indemnification is authorized by an agreement approved by the Board. As used herein, the term the "***Reincorporated Predecessor***" means a corporation that is merged with and into the Corporation in a statutory merger where (a) the Corporation is the surviving corporation of such merger; (b) the primary purpose of such merger is to change the corporate domicile of the Reincorporated Predecessor to Delaware. To the extent that a present or former director or officer of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding described in this Section 6.1 or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

Section 6.2: Advancement of Expenses

Except as otherwise provided in a written indemnification agreement between the Corporation and an Indemnitee upon written request, the Corporation shall pay all expenses (including attorneys' fees) incurred by such an Indemnitee in defending any such Proceeding as they are incurred in advance of its final disposition; *provided*, *however*, that if the DGCL then so requires, the payment of such expenses incurred by such Indemnitee in advance of the final disposition of such Proceeding shall be made only upon delivery to the Corporation of an undertaking, by or on behalf of such Indemnitee, to repay all amounts so advanced if it should be determined ultimately by final judicial decision from which there is no appeal that such Indemnitee is not entitled to be indemnified under this Article VI or otherwise. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents of the Corporation or by persons serving at the request of the Corporation as directors, officers, employees or agents of another corporation, partnership, joint venture, trust or other enterprise may be so paid upon such terms and conditions, if any, as the Corporation deems appropriate. The right to advancement of expenses shall not apply to any claim for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding referenced in Section 6.1 prior to a determination that the person is not entitled to be indemnified by the Corporation.

Section 6.3: Non-Exclusivity of Rights

The rights conferred on any person in this Article VI shall not be exclusive of any other right that such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote or consent of stockholders or disinterested directors, or otherwise. Additionally, nothing in this Article VI shall limit the ability of the Corporation, in its discretion, to indemnify or advance expenses to persons whom the Corporation is not obligated to indemnify or advance expenses pursuant to this Article VI.

Section 6.4: Indemnification Contracts

The Board is authorized to cause the Corporation to enter into indemnification contracts with any director, officer, employee or agent of the Corporation, or any person serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation, partnership, joint venture, trust or other enterprise, including employee benefit plans, providing indemnification or advancement rights to such person. Such rights may be greater than those provided in this Article VI.

Section 6.5: Right of Indemnitee to Bring Suit

The following shall apply to the extent not in conflict with any indemnification contract provided for in Section 6.4 of these Bylaws.

6.5.1 Right to Bring Suit. If a claim under Section 6.1 or 6.2 of these Bylaws is not paid in full by the Corporation within sixty (60) days after a written claim has been received by the Corporation, the Indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Indemnitee shall be entitled to be paid, to the fullest extent permitted by law, the expense of prosecuting or defending such suit. In (a) any suit brought by the Indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the Indemnitee to enforce a right to an advancement of expenses) it shall be a defense that, and (b) in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that, the Indemnitee has not met any applicable standard for indemnification set forth in applicable law.

6.5.2 Effect of Determination. Neither the failure of the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the Indemnitee is proper in the circumstances because the Indemnitee has met the applicable standard of conduct set forth in applicable law, nor an actual determination by the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) that the Indemnitee has not met such applicable standard of conduct, shall create a presumption that the Indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the Indemnitee, be a defense to such suit.

6.5.3 Burden of Proof. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article VI, or otherwise, shall be on the Corporation.

Section 6.6: Nature of Rights

The rights conferred upon Indemnitees in this Article VI shall be contract rights and such rights shall continue as to an Indemnitee who has ceased to be a director, officer or trustee and shall inure to the benefit of the Indemnitee's heirs, executors and administrators. Any amendment, repeal or modification of any provision of this Article VI that adversely affects any right of an Indemnitee or an Indemnitee's successors shall be prospective only, and shall not adversely affect any right or protection conferred on a person pursuant to this Article VI and existing at the time of such amendment, repeal or modification.

Section 6.7: Insurance

The Corporation may purchase and maintain insurance, at its expense, on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the provisions of the DGCL.

ARTICLE VII: NOTICES

Section 7.1: Notice

7.1.1 Form and Delivery. Except as otherwise specifically required in these Bylaws (including, without limitation, Section 7.1.2 of these Bylaws) or by applicable law, all notices required to be given pursuant to these Bylaws shall be in writing and may (a) in every instance in connection with any delivery to a member of the Board, be effectively given by hand delivery (including use of a delivery service), by depositing such notice in the mail, postage prepaid, or by sending such notice by overnight express courier, facsimile, electronic mail or other form of electronic transmission and (b) be effectively delivered to a stockholder when given by hand delivery, by depositing such notice in the mail, postage prepaid or, if specifically consented to by the stockholder as described in Section 7.1.2 of these Bylaws, by sending such notice by facsimile, electronic mail or other form of electronic transmission. Any such notice shall be addressed to the person to whom notice is to be given at such person's address as it appears on the records of the Corporation. The notice shall be deemed given (a) in the case of hand delivery, when received by the person to whom notice is to be given or by any person accepting such notice on behalf of such person, (b) in the case of delivery by mail, upon deposit in the mail, (c) in the case of delivery by overnight express courier, when dispatched, and (d) in the case of delivery via facsimile, electronic mail or other form of electronic transmission, at the time provided in Section 7.1.2 of these Bylaws.

7.1.2 Electronic Transmission. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation, or these Bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given in accordance with Section 232 of the DGCL. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if (a) the Corporation is unable to deliver by electronic transmission two consecutive notices given by the Corporation in accordance with such consent and (b) such inability becomes known to the Secretary or an Assistant Secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice; ***provided***, ***however***, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action. Notice given pursuant to this Section 7.1.2 shall be deemed given: (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice; (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice; (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of such posting and the giving of such separate notice; and (iv) if by any other form of electronic transmission, when directed to the stockholder.

7.1.3 Affidavit of Giving Notice. An affidavit of the Secretary or an Assistant Secretary or of the transfer agent or other agent of the Corporation that the notice has been given in writing or by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Section 7.2: Waiver of Notice

Whenever notice is required to be given under any provision of the DGCL, the Certificate of Incorporation or these Bylaws, a written waiver of notice, signed by the person entitled to notice, or waiver by electronic transmission by such person, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, directors or members of a committee of directors need be specified in any waiver of notice.

ARTICLE VIII: INTERESTED DIRECTORS

Section 8.1: Interested Directors

No contract or transaction between the Corporation and one or more of its members of the Board or officers, or between the Corporation and any other corporation, partnership, association or other organization in which one or more of its directors or officers are members of the board of directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board or committee thereof that authorizes the contract or transaction, or solely because his, her or their votes are counted for such purpose, if: (a) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the Board or the committee, and the Board or committee in good faith authorizes the contract or transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum; (b) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the stockholders; or (c) the contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified by the Board, a committee thereof, or the stockholders.

Section 8.2: Quorum

Interested directors may be counted in determining the presence of a quorum at a meeting of the Board or of a committee which authorizes the contract or transaction.

ARTICLE IX: MISCELLANEOUS

Section 9.1: Fiscal Year

The fiscal year of the Corporation shall be determined by resolution of the Board.

Section 9.2: Seal

The Board may provide for a corporate seal, which may have the name of the Corporation inscribed thereon and shall otherwise be in such form as may be approved from time to time by the Board.

Section 9.3: Form of Records

Any records administered by or on behalf of the Corporation in the regular course of its business, including its stock ledger, books of account and minute books, may be kept on or by means of, or be in the form of, any other information storage device, method or one or more electronic networks or databases (including one or more distributed electronic networks or databases), electronic or otherwise, *provided* that the records so kept can be converted into clearly legible paper form within a reasonable time and otherwise comply with the DGCL. The Corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to any provision of the DGCL.

Section 9.4: Reliance upon Books, Records and Experts

A member of the Board, or a member of any committee designated by the Board shall, in the performance of such person's duties, be fully protected in relying in good faith upon the books and records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of the Corporation's officers or employees, or committees of the Board, or by any other person as to matters the member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 9.5: Certificate of Incorporation Governs

In the event of any conflict between the provisions of the Certificate of Incorporation and Bylaws, the provisions of the Certificate of Incorporation shall govern.

Section 9.6: Severability

If any provision of these Bylaws shall be held to be invalid, illegal, unenforceable or in conflict with the provisions of the Certificate of Incorporation, then such provision shall nonetheless be enforced to the maximum extent possible consistent with such holding and the remaining provisions of these Bylaws (including without limitation, all portions of any section of these Bylaws containing any such provision held to be invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation, that are not themselves invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation) shall remain in full force and effect.

Section 9.7: Time Periods

In applying any provision of these Bylaws which requires that an act be done or not be done a specified number of days prior to an event or that an act be done during a period of a specified number of days prior to an event, calendar days shall be used, the day of the doing of the act shall be excluded, and the day of the event shall be included.

ARTICLE X: AMENDMENT

Notwithstanding any other provision of these Bylaws, any alteration, amendment or repeal of these Bylaws, and any adoption of new Bylaws, shall require the approval of the Board or the stockholders of the Corporation as expressly provided in the Certificate of Incorporation.

CERTIFICATION OF RESTATED BYLAWS
OF
ARCUTIS BIOTHERAPEUTICS, INC.
(a Delaware corporation)

I, Keith Klein, certify that I am Secretary of Arcutis Biotherapeutics, Inc., a Delaware corporation (the "***Corporation***"), that I am duly authorized to make and deliver this certification, that the attached Bylaws are a true and complete copy of the Restated Bylaws of the Corporation in effect as of the date of this certificate.

Dated: February 4, 2020

/s/ Keith Klein

Keith Klein
Secretary

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

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: May 12, 2020

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, John W. Smither, 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

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: May 12, 2020

By: /s/ John W. Smither

John W. Smither
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 March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and John W. Smither, 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: May 12, 2020 By: /s/ Todd Franklin Watanabe

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

Date: May 12, 2020 By: /s/ John W. Smither

John W. Smither
Chief Financial Officer
(Principal Accounting and Financial Officer)