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, 2021
OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For transition period from to
Commission File Number: 001-39186

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of shares of the registrant’s Common Stock outstanding as of April 30, 2021 was 50,205,046.

FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed in Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2021. The forward-looking statements in this Quarterly Report on Form 10-Q are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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

Summary of Risk Factors

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

- We are a late-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and we have incurred significant losses since our inception. We anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability;
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts;
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our future operating results to fall below expectations;
- Our estimated market opportunities for our product candidates are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited;
- Our business is dependent on the development, regulatory approval and commercialization of our current product candidates;

- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates;
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations;
- Interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- Certain of the endpoints in our planned clinical trials rely on a subjective assessment of the effect of the product candidate in the subject by either the physician or patient, and may prove difficult to meet in patients with more severe disease, which exposes us to a variety of risks for the successful completion of our clinical trials;
- Enrollment and retention of subjects in clinical trials is expensive and time-consuming and may result in additional costs and delays in our product development activities, or in the failure of such activities;
- Serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates;
- As a company, we have never obtained marketing approval for any product candidate and we may be unable to successfully do so in a timely manner, if at all, for any of our product candidates;
- Even if our lead product candidate or our other product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success;
- If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered;
- We currently have limited sales, marketing or distribution capabilities and have no experience as a company in commercializing products;
- We will need to increase the size of our organization, and we may experience difficulties in executing our growth strategy and managing any growth;
- If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop our current and any future product candidates, commercialize our product candidates or otherwise implement our business plan;
- We currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. The loss of these manufacturers, or their failure to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business;
- We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize roflumilast cream, roflumilast foam, ARQ-252, ARQ-255 or any future product candidates;
- Risks related to our intellectual property could materially adversely impact our business, competitive position, financial condition, and results of operations;
- Risks related to government regulation of our industry and required approvals could materially adversely impact our business, competitive position, financial condition, and results of operations; and
- Future litigation could have a material adverse effect on our business and results of operations.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARCUTIS BIOTHERAPEUTICS, INC.

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

	March 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 288,690	$ 65,082
Restricted cash	1,542	1,542
Marketable securities	156,237	219,359
Prepaid expenses and other current assets	19,506	6,843
Total current assets	465,975	292,826
Property, plant, and equipment, net	2,094	2,016
Operating lease right-of-use asset	3,269	3,349
Other assets	78	78
Total assets	$ 471,416	$ 298,269
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,146	$ 7,140
Accrued liabilities	12,168	15,462
Total current liabilities	15,314	22,602
Operating lease liability, noncurrent	5,050	4,964
Other long-term liabilities	58	82
Total liabilities	20,422	27,648
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020;	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at March 31, 2021 and December 31, 2020; 50,146,461 and 43,677,817 shares issued at March 31, 2021 and December 31, 2020, respectively; 49,887,007 and 43,338,438 shares outstanding at March 31, 2021 and December 31, 2020, respectively	5	4
Additional paid-in capital	688,939	472,569
Accumulated other comprehensive income (loss)	42	(2)
Accumulated deficit	(237,992)	(201,950)
Total stockholders' equity	450,994	270,621
Total liabilities, convertible preferred stock and stockholders' equity	$ 471,416	$ 298,269

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

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 21,631	$ 25,182
General and administrative	14,454	3,469
Total operating expenses	36,085	28,651
Loss from operations	(36,085)	(28,651)
Other income, net	43	638
Net loss	$ (36,042)	$ (28,013)
Other comprehensive income (loss):		
Unrealized gains on marketable securities	44	20
Comprehensive loss	$ (35,998)	$ (27,993)
Per share information:		
Net loss per share, basic and diluted	$ (0.76)	$ (1.15)
Weighted-average shares used in computing net loss per share, basic and diluted	47,280,769	24,256,402

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2019	24,385,388	$ 166,491	2,120,853	$ —	$ 1,244	$ (1)	$ (66,272)	$ (65,029)
Conversion of preferred stock into common stock upon initial public offering	(24,385,388)	(166,491)	24,385,388	2	166,489	—	—	166,491
Issuance of shares of common stock for initial public offering, net of issuance costs of $16,040	—	—	10,781,250	1	167,240	—	—	167,241
Issuance of shares of common stock upon the exercise of stock options	—	—	51,147	—	152	—	—	152
Vesting of founder shares subject to repurchase	—	—	68,931	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	64,428	—	30	—	—	30
Stock-based compensation expense	—	—	—	—	990	—	—	990
Unrealized gain on marketable securities	—	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	—	(28,013)	(28,013)
Balance—March 31, 2020	—	—	37,471,997	$ 3	$ 336,145	$ 19	$ (94,285)	$ 241,882

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2020	—	$ —	43,338,438	$ 4	$ 472,569	$ (2)	$ (201,950)	$ 270,621
Issuance of shares of common stock for public offering, net of issuance costs of $603	—	—	6,325,000	1	207,489	—	—	207,490
Issuance of shares of common stock upon the exercise of stock options	—	—	111,282	—	325	—	—	325
Issuance of restricted stock units	—	—	32,362	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	79,925	—	53	—	—	53
Stock-based compensation expense	—	—	—	—	8,503	—	—	8,503
Unrealized gain on marketable securities	—	—	—	—	—	44	—	44
Net loss	—	—	—	—	—	—	(36,042)	(36,042)
Balance—March 31, 2021	—	$ —	49,887,007	$ 5	$ 688,939	$ 42	$ (237,992)	$ 450,994

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (36,042)	$ (28,013)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	98	27
Non-cash lease expense	80	38
Net amortization/accretion on marketable securities	616	(192)
Stock-based compensation expense	8,503	990
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(12,663)	(1,097)
Accounts payable	(3,880)	3,412
Accrued liabilities	(3,001)	3,868
Operating lease liabilities	86	(43)
Net cash used in operating activities	(46,203)	(21,010)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	—	(35,285)
Proceeds from maturities of marketable securities	62,550	15,000
Purchases of property and equipment	(554)	(41)
Net cash provided by (used in) investing activities	61,996	(20,326)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	325	247
Proceeds from initial public offering, net of issuance costs	—	168,646
Proceeds from issuance of common stock, net of issuance costs	207,490	—
Net cash provided by financing activities	207,815	168,893
Net increase in cash, cash equivalents, and restricted cash	223,608	127,557
Cash, cash equivalents, and restricted cash at beginning of period	66,624	63,336
Cash, cash equivalents, and restricted cash at end of period	$ 290,232	$ 190,893
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Deferred financing costs included in accounts payable and accrued liabilities	$ —	$ 4

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

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 highly differentiated topical treatments with significant promise to treat immune-mediated dermatological diseases and conditions. The Company believes it has built the industry's leading platform for dermatologic product development. The Company's strategy is to focus on validated biological targets and to use our platform and deep dermatology expertise to develop differentiated products that have the potential to address the major shortcomings of existing therapies in its targeted indications. The Company believes this strategy uniquely positions it to rapidly advance its goal of bridging the treatment innovation gap in dermatology while maximizing its probability of technical success.

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

Initial Public Offering and Follow-On Financings

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

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

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

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $238.0 million and $202.0 million as of March 31, 2021 and December 31, 2020, respectively. The Company had cash, cash equivalents, restricted cash, and marketable securities of $446.5 million and $286.0 million as of March 31, 2021 and December 31, 2020, respectively. Prior to selling common stock in its IPO and follow-on financings, the Company had historically financed its operations primarily through the sale of its convertible preferred stock. Management expects operating losses to continue for the foreseeable future.

The Company believes that its existing capital resources will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of its financial statements. The Company will be required to raise additional capital to fund future operations. However, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to significantly reduce its operating expenses. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company's ability to achieve its intended business objectives and have an adverse effect on its results of operations and future prospects.

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

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 6, 2021, the Company's operations have not been significantly impacted by the COVID-19 pandemic. The Company is monitoring the impact COVID-19 may have on the clinical development of its product candidates, including potential delays or modifications to its ongoing and planned trials. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned clinical trials.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP).

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. On an ongoing basis, management evaluates such estimates and assumptions for continued reasonableness. In particular, management makes estimates with respect to accruals for research and development activities, fair value of common stock and convertible preferred stock (prior to the IPO completed in January 2020), stock-based compensation expense and income taxes. Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation. Actual results could differ from those estimates.

Segments

To date, the Company has viewed its financial information on an aggregate basis for the purposes of evaluating financial performance and allocating the Company's resources. Accordingly, the Company has determined that it operates in one segment.

Unaudited Interim Condensed Financial Statements

The interim condensed balance sheet as of March 31, 2021, the interim condensed statements of operations and comprehensive loss, and the condensed changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for the three months ended March 31, 2021, and 2020 are unaudited. These unaudited interim condensed financial statements have been prepared on the same basis as the Company's audited annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair statement of the Company's financial information. The financial data and the other financial information disclosed in these notes to the condensed financial statements related to the three-month periods are also unaudited. The condensed results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Therefore, these unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2020.

Cash and Cash Equivalents

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

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

Restricted Cash

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

Marketable Securities

Marketable securities consist of investment grade short to intermediate-term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase 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 other comprehensive income (loss). Realized gains and losses as well as credit losses, if any, on marketable securities are included in other income, net. The Company evaluated the underlying credit quality and credit ratings of the issuers during the period. To date, no such credit losses have occurred or have been recorded. The cost of investments sold is based on the specific-identification method. As of March 31, 2021, there were net unrealized gains on marketable securities of $42,000, and as of December 31, 2020, there were net unrealized losses on marketable securities of $2,000. Unrealized gains and losses on marketable securities are reported as a component of accumulated other comprehensive income (loss) on the balance sheets. Realized gains or losses on investments for the three months ended March 31, 2021 were not material. There were no realized gains or losses on investments for the three months ended March 31, 2020. Interest on marketable securities is included in other income, net.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the 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, include cash equivalents, accounts payable, and accrued liabilities. The carrying amount of cash equivalents, accounts payable, and accrued liabilities approximate their fair values due to their short maturities.

Assets and liabilities recorded at fair value on a recurring basis on the 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.

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

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets which range from three to five years. Leasehold improvements are depreciated on a straight-line basis over the shorter of their estimated useful lives or lease terms. Maintenance and repairs are expensed as incurred. The Company reviews the carrying values of its property and equipment for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There were no impairments recognized during the three months ended March 31, 2021 and 2020.

Leases

The Company determines if an arrangement is or contains a lease at inception. Right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The classification of the Company's leases as operating or finance leases, along with the initial measurement and recognition of the associated ROU assets and lease liabilities, is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate, based on the information available at commencement date, to determine the present value of lease payments when its leases do not provide an implicit rate. The Company uses the implicit rate when readily determinable. The ROU asset is based on the measurement of the lease liability, includes any lease payments made prior to or on lease commencement and is adjusted for lease incentives and initial direct costs incurred, as applicable. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term. The Company considers a lease term to be the non-cancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The Company's lease agreements includes lease and non-lease components and the Company has elected to not separate such components for all classes of assets. Further, the Company elected the short-term lease exception policy, permitting it to not apply the recognition requirements of this standard to leases with terms of 12 months or less (short-term leases) for all classes of assets.

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, 2021 and 2020, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Convertible Preferred Stock

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

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Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, license fees, stock-based compensation expense, materials, supplies, and the cost of services provided by outside contractors. All costs associated with research and development are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or services are rendered. Such payments are evaluated for current or long-term classification based on when they will be realized.

The Company has entered into, and may continue to enter into, license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date none of the Company's license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expense when paid or become payable, provided there is no alternative future use of the rights in other research and development projects.

Stock-Based Compensation

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

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. The Company records a valuation allowance to reduce deferred tax assets to an amount for which realization is more likely than not. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes the tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties incurred in relation to the unrecognized tax benefits.

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

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Variable Interest Entities

The Company reviews agreements it enters into with third-party entities, pursuant to which the Company may have a variable interest in the entity, in order to determine if the entity is a variable interest entity (VIE). If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that entity. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (i) the power to direct the economically significant activities of the entity and (ii) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If the Company determines it is the primary beneficiary of a VIE, it consolidates that VIE into the Company's financial statements. The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation or deconsolidation event. The Company currently does not consolidate any VIEs.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

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

3. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	March 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 288,690	$ —	$ —	$ 288,690
Commercial paper	—	10,990	—	10,990
U.S. Treasury securities	145,247	—	—	145,247
Total assets	$ 433,937	$ 10,990	$ —	$ 444,927

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

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

Commercial paper, money market funds, and U.S. Treasury securities are valued taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

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, 2021			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 288,690	$ —	$ —	$ 288,690
Total cash and cash equivalents	$ 288,690	$ —	$ —	$ 288,690
Marketable securities:				
Commercial paper	10,990	—	—	10,990
U.S. Treasury securities	145,205	42	—	145,247
Total marketable securities	$ 156,195	$ 42	$ —	$ 156,237

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

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

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

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

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4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	March 31, 2021	December 31, 2020
Prepaid clinical trial costs	$ 14,105	$ 4,865
Prepaid insurance	2,675	249
Tax credits	577	510
Other prepaid expenses and current assets	2,149	1,219
Total prepaid expenses and other current assets	$ 19,506	$ 6,843

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Clinical trial accruals	$ 7,519	$ 9,754
Accrued compensation	1,713	4,434
Early exercise liability, current	148	176
Accrued expenses and other current liabilities	2,788	1,098
Total accrued liabilities	$ 12,168	$ 15,462

5. Property and Equipment, net

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

	Useful life (in years)	March 31, 2021	December 31, 2020
Computer hardware	3	$ 384	$ 286
Furniture and fixtures	5	248	230
Software	3	70	—
Construction in process		—	298
Leasehold improvements		1,568	1,280
Property and equipment, gross		2,270	2,094
Less accumulated depreciation		(176)	(78)
Property and equipment, net		$ 2,094	$ 2,016

Leasehold improvements are depreciated over the term of the lease. Depreciation expense was $98,000 and $27,000 for the three months ended March 31, 2021 and 2020, respectively.

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6. License Agreements

AstraZeneca License Agreement

In July 2018, the Company entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca AB (AstraZeneca), granting the Company a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, commercialize and otherwise exploit products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, the AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. Under this agreement, the Company has sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at its expense, and it shall use commercially reasonable efforts to develop, obtain, and maintain regulatory approvals for, and commercialize the AZ-Licensed Products in the Dermatology Field in each of the United States, Italy, Spain, Germany, the United Kingdom, France, China, and Japan.

The Company paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of Series B convertible preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. The Company subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product, which was recorded in research and development expense. The Company has agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specified regulatory approval milestones with respect to the AZ-Licensed Products 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, 2021 and 2020.

Hengrui Exclusive Option and License Agreement

In January 2018, the Company entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd. (Hengrui), whereby Hengrui granted the Company an exclusive option to obtain certain exclusive rights to research, develop, and commercialize products containing the compound designated by Hengrui as SHR0302, a Janus kinase type 1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, Canada, and the European Union (including for clarity the United Kingdom). The Company made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui Option and License Agreement, which was recorded as research and development expense. In December 2019, the Company exercised its exclusive option under the agreement, for which it made a $1.5 million cash payment, which was recorded in research and development expense, and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, the Company has agreed to make cash payments of up to an aggregate of $20.5 million upon achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $200.0 million in sales-based milestones based on certain aggregate annual net sales volumes with respect to a licensed product.

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

There were no payments made or due in connection with Hengrui for the three months ended March 31, 2021 and 2020.

Hawkeye Collaboration Agreement

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

Contemporaneously with the execution of the Hawkeye Agreement, the Company entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye's common stock at $0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye. In the event that Hawkeye issues shares of Series A preferred stock with proceeds over $5.0 million, Hawkeye is required to issue to the Company a number of fully-paid fully-vested shares of common stock determined by dividing (i) $2,000,000 by (ii) an amount equal to the cash price per share for Series A preferred stock. Other than the potential issuance of this common stock, there are no upfront payments, milestones, or royalties pursuant to the Hawkeye Agreement. The Company determined that Hawkeye is a VIE for which consolidation is not required as it is not the primary beneficiary.

7. Commitments and Contingencies

Operating Lease

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

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

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

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

The minimum annual rental payments of the Company's operating lease liability as of March 31, 2021 are as follows (in thousands):

	Amounts
2021 (April through December)	$ 114
2022	781
2023	965
2024	995
2025	1,024
Thereafter	2,794
Total minimum lease payments	$ 6,673
Less: Amounts representing interest	(1,623)
Present value of future minimum lease payments	$ 5,050
Operating lease liability, noncurrent	5,050
Total operating lease liability	$ 5,050

Straight-line rent expense recognized for operating leases was $175,000 and $43,000 for the three months ended March 31, 2021 and 2020, respectively. There were no significant variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the three months ended March 31, 2021 and 2020.

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,	
	2021	2020
Cash flows from operating activities		
Cash paid for amounts included in the measurement of lease liabilities	$ —	$ 47

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The following summarizes additional information related to the operating lease:

	March 31, 2021
Weighted-average remaining lease term (in years)	7.3
Weighted-average discount rate	7.0 %

Indemnification

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

8. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

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

Common Stock

The holders of the Company's common stock have one vote for each share of common stock. Common stockholders are entitled to dividends when, as, and if declared by the board of directors. The holders have no preemptive or other subscription rights and there are no redemption or sinking fund provisions with respect to such shares. As of March 31, 2021, 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, 2021	December 31, 2020
Options issued and outstanding	4,540,255	3,655,945
Common stock awards available for grant under employee benefit plans	3,509,044	2,501,329
Restricted stock units outstanding	310,068	162,930
Total common stock reserved	8,359,367	6,320,204

Authorized Share Capital

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

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9. Stock-Based Compensation

In January 2020, the Company's board of directors approved the 2020 Equity Incentive Plan, (2020 Plan), which became effective January 30, 2020 in connection with the IPO. The 2020 Plan serves as the successor incentive award plan to the Company's 2017 Equity Incentive Plan (2017 Plan) and has 2,134,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock-based awards, plus 1,550,150 shares of common stock that were reserved for issuance pursuant to future awards under the 2017 Plan at the time the 2020 Plan became effective, plus shares represented by awards outstanding under the 2017 Plan that are forfeited or lapsed unexercised and which following the effective date of the 2020 Plan are not issued under the 2017 Plan. In addition, the 2020 Plan reserve will increase on January 1 of each year through 2030, by an amount equal to the lesser of (a) four percent of the shares of stock outstanding (on an as converted basis) on the day immediately prior to the date of increase and (b) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 11,000,000 shares of stock may be issued upon the exercise of incentive stock options. Accordingly, on January 1, 2021, the plan reserve increased by 1,747,112 shares. As of March 31, 2021, the Company had 2,755,454 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, 2020	3,655,945	$ 12.09	8.78	$ 59,274
Granted	1,024,400	$ 31.51		
Exercised	(112,365)	$ 2.96		
Forfeited	(27,725)	$ 28.65		
Balance—March 31, 2021	4,540,255	$ 16.60	8.63	$ 59,383
Exercisable—March 31, 2021[(1)]	2,099,037	$ 8.57	7.87	$ 42,849

(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, 2021. As of December 31, 2020, 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, 2021 was $3.3 million.

The total grant-date fair value of the options vested during the three months ended March 31, 2021 was $4.9 million. The weighted-average grant-date fair value of employee options granted during the three months ended March 31, 2021 was $21.74.

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Restricted Stock Unit Activity

The following table summarizes information regarding our RSUs:

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2020	162,930	$ 27.26
Granted	181,900	$ 32.00
Vested	(32,362)	$ 27.61
Forfeited	(2,400)	$ 32.44
Unvested Balance—March 31, 2021	310,068	$ 29.96

The grant date fair value of an RSU equals the closing price of our common stock on the grant date. RSUs generally vest equally over four years. There were no RSU grants prior to January 1, 2020.

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 1,520	$ 416
General and administrative	6,983	574
Total stock-based compensation expense	$ 8,503	$ 990

As of March 31, 2021, there was $41.2 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 3.5 years. As of March 31, 2021, there was $8.5 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 3.7 years.

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

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

Fair value of common stock—For options granted prior to IPO in the year ended December 31, 2019, given the absence of a public trading market, the Company's board of directors with input from management considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to: (i) third-party valuations of the Company's common stock; (ii) the Company's stage of development; (iii) the status of research and development efforts; (iv) the rights, preferences, and privileges of the Company's convertible preferred stock relative to those of the Company's common stock; (v) the Company's operating results and financial condition, including the Company's levels of available capital resources; (vi) equity market conditions affecting comparable public companies; (vii) general U.S. market conditions; and (viii) the lack of marketability of the Company's common stock. For options granted after IPO, the Company uses its closing stock price as reported on Nasdaq on the grant date for the fair value of its stock.

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

Expected Volatility—The Company does not yet have sufficient trading history for its common stock to solely use its own historical volatility. Therefore, the expected volatility was estimated based on a combination of its own historical common stock volatility as well as the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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

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

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, 2021	Year Ended December 31, 2020
Expected term (in years)	5.8 – 6.1	5.5 – 6.8
Expected volatility	84.5 – 85.2%	78.4 – 80.8%
Risk-free interest rate	0.6 – 1.0%	0.3 – 1.4%
Dividend yield	—%	—%

Early Exercise of Employee Options

The terms of the 2017 and 2020 Plans permit certain option holders to exercise options before their options are vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement. The shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. While such shares have been issued, they are not considered outstanding for accounting purposes until they vest and are therefore excluded from shares used in determining loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $206,000 and $258,000 as a liability from the early exercise in the accompanying balance sheets as of March 31, 2021 and December 31, 2020, respectively. As of March 31, 2021 and December 31, 2020, there were $148,000 and $176,000 recorded in accrued liabilities, respectively, and $58,000 and $82,000 recorded in other long-term liabilities, respectively related to shares that were subject to repurchase.

ARCUTIS BIOTHERAPEUTICS, INC.
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Founder Awards

In August 2016, the Company issued 1,187,738 shares of restricted common stock to founders, of which 1,102,903 shares would vest under a service condition, and 84,835 shares would vest under a performance condition. The shares were issued under the terms of the respective restricted stock purchase agreements, or the Stock Purchase Agreement, and unvested shares were subject to repurchase by the Company at the original purchase price per share upon the holder's termination of his relationship with the Company. The restricted shares were not considered outstanding for accounting purposes until they vested and are therefore excluded from shares used in determining loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. One-fourth of the 1,102,903 shares of restricted common stock were vested on the first-anniversary date and the remaining 827,177 shares vested on a monthly basis thereafter. All shares of restricted stock subject to the award were vested as of June 30, 2020.

2020 Employee Stock Purchase Plan

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

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

The Company commenced an offering period on January 31, 2020, which ended on May 31, 2020, and resulted in 19,862 shares of stock being issued under the ESPP. The Company also commenced an offering period on June 1, 2020, which ended on November 30, 2020, and resulted in 14,326 shares of stock being issued under the ESPP. In addition, the Company commenced an offering period on December 1, 2020, which will end on May 31, 2021. Stock-based compensation expense related to the ESPP was $117,000 and $66,000 for the three months ended March 31, 2021 and 2020, respectively.

10. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of March 31,	
	2021	2020
Stock options to purchase common stock	4,540,255	3,061,521
Early exercised options subject to future vesting	259,460	613,627
RSU's subject to future vesting	310,068	198,992
ESPP shares subject to future issuance	3,733	11,392
Total	5,113,516	3,885,532

ARCUTIS BIOTHERAPEUTICS, INC.
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11. Subsequent Event

On May 6, 2021, the Company entered into a sales agreement (Sales Agreement) with Cowen and Company, LLC (Cowen), under which the Company may from time to time issue and sell shares of its common stock through at-the-market (ATM) offerings for an aggregate offering price of up to $100.0 million. Cowen will act as the Company's sales agent for the ATM program. The issuance and sale of shares of common stock by the Company pursuant to the Sales Agreement are deemed an “at-the-market” offering under the Securities Act of 1933, as amended. Cowen is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold through Cowen under the Sales Agreement. The ATM program has been registered under the Securities Act pursuant to the Company's shelf registration statement on Form S-3, as amended (Registration No. 333-252612), as supplemented by the Prospectus Supplement dated May 6, 2021 relating to the sale of shares of our common stock.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto as of and for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2020, which has been filed with the Securities and Exchange Commission. 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 highly differentiated topical treatments with significant potential to treat immune-mediated dermatological diseases and conditions. We believe we have built the industry's leading platform for dermatologic product development. Our strategy is to focus on validated biological targets, and to use our platform and deep dermatology expertise to develop differentiated products that have the potential to address the major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product candidate, roflumilast cream, has successfully completed pivotal Phase 3 clinical trials in plaque psoriasis. We are currently preparing a New Drug Application (NDA), with a submission to the U.S. Food and Drug Administration (FDA) expected in the second half of 2021. Roflumilast cream is a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor, an established biological target in dermatology, with multiple PDE4 inhibitors approved by the FDA for dermatological conditions. We are developing roflumilast cream for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. We have also successfully completed a long-term safety study of roflumilast cream in plaque psoriasis patients.

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

We are also developing a topical foam formulation of roflumilast, and have successfully completed Phase 2 studies in both seborrheic dermatitis and scalp psoriasis. In seborrheic dermatitis, we had a successful End of Phase 2 meeting with the FDA and plan to initiate a single pivotal Phase 3 clinical trial in the second or third quarter of 2021, with topline data expected in the second or third quarter of 2022. In scalp psoriasis, we also had a successful End of Phase 2 meeting with the FDA and plan to initiate a single pivotal Phase 3 clinical trial in the second half of 2021, with topline data expected in the second half of 2022.

We are developing ARQ-252, a potent and highly selective topical JAK1 inhibitor, for the treatment of chronic hand eczema and vitiligo. Our recently completed Phase 1/2b study of ARQ-252 for the treatment of chronic hand eczema did not meet its primary endpoint. Further analyses of the data are underway.

We also recently initiated a Phase 2 proof of concept study of ARQ-252 for the treatment of vitiligo, with topline results expected in the second half of 2023. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

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

We have incurred net losses in each year since inception, including net losses of $36.0 million and $28.0 million for the three months ended March 31, 2021, and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $238.0 million and cash, cash equivalents, restricted cash, and marketable securities of $446.5 million.

We expect to continue to incur losses for the foreseeable future and expect to incur increased expenses as we advance our product candidates through clinical trials and regulatory submissions. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval or clearance from the FDA or other foreign regulatory authorities for our product candidates. If we obtain regulatory approval or clearance for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. In addition, we expect that our expenses will increase substantially as we continue preclinical studies and clinical trials for, and research and development of, our product candidates and maintain, expand, and protect our intellectual property portfolio. As a result, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through equity or debt financings or other sources, such as future potential collaboration agreements. Our failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations, and financial condition. See “Liquidity, Capital Resources and Requirements” below and Note 1 to the financial statements for additional information. Based on our current planned operations, we expect that our current cash, cash equivalents, and marketable securities will be sufficient to fund our operations well into 2023.

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

COVID-19 Update

In March 2020, the World Health Organization declared a pandemic related to the COVID-19 outbreak. COVID-19 has placed strains on the providers of healthcare services, including the sites where we conduct our clinical trials. These strains have resulted in some clinical sites slowing or halting enrollment in clinical trials and restricting the on-site monitoring of clinical trials. We follow FDA guidance on clinical trial conduct during the COVID-19 pandemic, including the remote monitoring of clinical data. We are monitoring the impact COVID-19 may have on the clinical development of our product candidates, including potential delays or modifications to ongoing and planned trials. Thus far, we have seen limited impact on our clinical trials, including some disruptions in screening, enrollment and monitoring; however at this time, we do not expect delays to previously disclosed clinical timelines, including those for roflumilast cream, roflumilast foam, 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 developed a return-to-work protocol, and as the pandemic conditions improved in the southern California region, we began a phased return to in-person work in the first quarter of 2021. We may need to undertake additional actions that could impact our operations as required by applicable laws or regulations, or which we determine to be in the best interests of our employees.

License Agreements

AstraZeneca License Agreement

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

We paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of our Series B Preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product. We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specific regulatory approval milestones with respect to the AZ-Licensed Products and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. See Note 6 to the unaudited condensed financial statements for additional information.

Hengrui Exclusive Option and License Agreement

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

The agreement continues in effect until the expiration of our obligation to pay royalties as described above, unless earlier terminated in accordance with the following: (1) by either party upon written notice for the other party's material breach or insolvency event if such party fails to cure such breach or the insolvency event is not dismissed within specified time periods; and (2) by us for convenience upon 90 days prior written notice to Hengrui and having discussed and consulted any potential cause or concern with Hengrui in good faith. See Note 6 to the unaudited condensed financial statements for additional information.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts, and activities related to regulatory filings for our product candidates. Research and development costs are expensed as incurred. These costs include direct program expenses, which are payments made to third parties that specifically relate to our research and development, such as payments to clinical research organizations, clinical investigators, manufacturing of clinical material, preclinical testing, and consultants. In addition, employee costs, including salaries, payroll taxes, benefits, stock-based compensation and travel, for employees contributing to research and development activities are classified as research and development costs. We allocate direct external costs on a program specific basis (topical roflumilast program, topical JAK inhibitor program and early stage programs). Our internal costs are primarily related to personnel or professional services and apply across programs, and thus are not allocatable on a program specific basis.

We expect to continue to incur substantial research and development expenses in the future as we develop our product candidates. In particular, we expect to incur substantial research and development expenses for the Phase 3 trials of roflumilast cream for atopic dermatitis, the Phase 3 trials of roflumilast foam for seborrheic dermatitis and scalp 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 marketing, auditing, tax, and general legal services. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and prepare for potential commercialization of our product candidates, increase our headcount, and support our operations as a public company; including increased expenses related to legal, accounting, insurance, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission (SEC) requirements, directors and officers liability insurance premiums, and investor relations activities.

Other Income, Net

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

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

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

	Three Months Ended March 31,		Change	
	2021	2020	$	%
	(unaudited) (in thousands)			
Operating expenses:				
Research and development	$ 21,631	$ 25,182	$ (3,551)	(14)%
General and administrative	14,454	3,469	10,985	317 %
Total operating expenses	$ 36,085	$ 28,651	$ 7,434	26 %
Loss from operations	(36,085)	(28,651)	(7,434)	26 %
Other income, net	43	638	(595)	(93)%
Net loss	$ (36,042)	$ (28,013)	$ (8,029)	29 %

Research and Development Expenses

	Three Months Ended March 31,		Change	
	2021	2020	$	%
	(unaudited) (in thousands)			
Direct external costs:				
Topical roflumilast program	$ 9,787	$ 20,585	$ (10,798)	(52)%
Topical JAK inhibitor program	3,651	1,405	2,246	160 %
Other early stage programs	177	—	177	*
Indirect costs:				
Compensation and personnel-related	5,109	2,267	2,842	125 %
Other	2,907	925	1,982	214 %
Total research and development expense	$ 21,631	$ 25,182	$ (3,551)	(14)%

(*) Change % is not applicable.

Research and development expenses decreased by $3.6 million, or 14%, for the three months ended March 31, 2021 compared to the three months ended March 31, 2020. The decrease was due to a decrease in direct costs related to the topical roflumilast program of $10.8 million, offset by an increase in direct costs related to the topical JAK inhibitor program (ARQ-252 and ARQ-255) of $2.2 million, an increase in compensation and personnel-related costs of $2.8 million, and an increase of $2.0 million in other costs. The decreased topical roflumilast program costs relate primarily to the completion of the Phase 3 studies of roflumilast cream for plaque psoriasis and the Phase 2 studies of roflumilast foam in seborrheic dermatitis and scalp psoriasis, as well as a decrease in manufacturing costs. This decrease was partially offset by the costs related to our Phase 3 studies of roflumilast cream in atopic dermatitis. The increased topical JAK inhibitor program costs relate primarily to our Phase 2 studies of ARQ-252 in hand eczema and vitiligo, as well as increased product development expenses. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount. The increase in other costs relate primarily to an increase in consulting activity and medical affairs spending.

General and Administrative Expenses

General and administrative expenses increased by $11.0 million, or 317%, for the three months ended March 31, 2021 compared to the three months ended March 31, 2020. The increase was primarily due to an increase in compensation and personnel-related expenses of $7.7 million, and an increase in professional services of $2.6 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to the recognition of $5.3 million of incremental stock-based compensation expense as a result of modification to the vesting schedule and exercise term of previously-granted awards in connection with the retirement of our former Chief Financial Officer, as well as an increase in headcount. The increase in professional services was mainly due to an increase in consulting activity and marketing expenses primarily related to roflumilast.

Other Income, Net

Other income, net decreased by $595,000, or 93%, for the three months ended March 31, 2021 compared to the three months ended March 31, 2020. The decrease was due to a lower yield on our investment portfolio.

Liquidity, Capital Resources, and Requirements

Sources of Liquidity

We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. As of March 31, 2021, we had cash, cash equivalents, restricted cash, and marketable securities of $446.5 million, and an accumulated deficit of $238.0 million. We anticipate that operating losses and net cash used in operating activities will increase over the next several years as we further develop roflumilast cream, roflumilast foam, ARQ-252, and ARQ-255; move into later and more costly stages of product development, develop new product candidates, hire personnel, and prepare for regulatory submissions and the commercialization of our product candidates.

We have historically financed our operations primarily through private placements of preferred stock, as well as our IPO completed in January 2020 and our follow-on financing in October 2020 and February 2021. We will continue to be dependent upon equity, debt financing, collaborations, or other forms of capital at least until we are able to generate positive cash flows from our operations. On May 6, 2021, we entered into a sales agreement, or Sales Agreement, with Cowen, to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $100.0 million through an at-the-market equity offering program under which Cowen acts as sales agent, or the ATM Offering Program. During the three months ended March 31, 2021, we did not issue or sell any shares of our common stock through our ATM Offering Program.

Cash Flows

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

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
	(in thousands)	
Cash used in operating activities	$ (46,203)	$ (21,010)
Cash provided by (used in) investing activities	61,996	(20,326)
Cash provided by financing activities	207,815	168,893
Net increase in cash and cash equivalents	$ 223,608	$ 127,557

Net Cash Used in Operating Activities

During the three months ended March 31, 2021, net cash used in operating activities was $46.2 million, which consisted of a net loss of $36.0 million and a change in net operating assets and liabilities of $19.5 million offset by net non-cash charges of $9.3 million. The change in net operating assets and liabilities was primarily due to an increase of $12.7 million in prepaid expenses and other current assets due to an increase in prepaid clinical trials and a decrease of $6.9 million in accounts payable and accrued liabilities due to the timing of payments to contract research organizations and payment of employee bonuses accrued for at December 31, 2020. The net non-cash charges were primarily related to stock-based compensation expense of $8.5 million.

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.

Net Cash Provided by (Used in) Investing Activities

During the three months ended March 31, 2021, net cash provided by investing activities was $62.0 million, which was comprised primarily of proceeds from the maturities of marketable securities of $62.6 million, partially offset by the purchases of property and equipment of $0.6 million.

During the 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.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2021, net cash provided by financing activities was $207.8 million, which was comprised primarily of the net cash proceeds received from the follow-on financing in February 2021 of $207.5 million.

During the 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.

Funding Requirements

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $238.0 million as of March 31, 2021. We had cash, cash equivalents, and marketable securities of $444.9 million as of March 31, 2021. Based on our current planned operations, we expect that our current cash, cash equivalents, and marketable securities will be sufficient to fund our operations well into 2023. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

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

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

- the scope, progress, results, and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our planned or ongoing clinical studies of roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast foam in seborrheic dermatitis and scalp psoriasis, ARQ-252 in hand eczema and vitiligo, and our formulation and preclinical efforts for ARQ-255 for alopecia areata.
- suspensions or delays in the enrollment or changes to the number of patients we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead product candidate or our other product candidates;

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

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of March 31, 2021:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating leases	$ 6,673	$ 114	$ 1,746	$ 2,019	$ 2,794
Total obligations	$ 6,673	$ 114	$ 1,746	$ 2,019	$ 2,794

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

The lease is subject to fixed rate escalation increases with an initial base rent of $76,000 per month and includes rent free periods aggregating approximately one year. The amended lease agreement required that we deliver a letter of credit to the landlord of $1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, in November 2020, we entered into a letter of credit for $1.5 million, which is secured with a restricted cash account in the same amount.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Use of Estimates

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

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed financial statements.

Emerging Growth Company Status

We are an emerging growth company as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we are (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We early adopted ASU No. 016-01, *Financial Instruments—Overall (Topic 825)—Recognition and Measurement of Financial Assets and Financial Liabilities*, ASU 2016-09, *Compensation—Stock Compensation (Topic 718)—Improvements to Employee Share Based Payment Accounting*, ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, ASU No. 2016-02, *Leases,* ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* and ASU No. 2019-12, *Income Taxes (Topic 740),* as the JOBS Act does not preclude an emerging growth company from early adopting a new or revised accounting standard earlier than the time such standard applies to private companies. We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

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, 2021, we had cash and cash equivalents of $288.7 million, restricted cash of $1.5 million, and marketable securities of $156.2 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, 2021.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the 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. Based on the evaluation of our disclosure controls and procedures as of March 31, 2021, our CEO and CFO have concluded that, as of March 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

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

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition, and the trading price of our common stock. This discussion should be read in conjunction with the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", and our Annual Report on Form 10-K for the year ended December 31, 2020. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects, and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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

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

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

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

Our net loss for the three months ended March 31, 2021 was approximately $36.0 million. As of March 31, 2021, we had an accumulated deficit of $238.0 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. We may never achieve profitability and, even if we do, we may not be able to sustain profitability in subsequent periods. We will continue to incur significant research and development and other expenses related to our ongoing operations and the development of our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital.

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

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

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

As of March 31, 2021, we had capital resources consisting of cash, cash equivalents, and marketable securities of $444.9 million. Based on our planned operations, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operations well into 2023. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

- the scope, progress, results, and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our planned or ongoing clinical studies of roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast foam in seborrheic dermatitis and scalp psoriasis, ARQ-252 in hand eczema vitiligo, and our formulation and preclinical efforts for ARQ-255 in alopecia areata;
- suspensions or delays in the enrollment, issues with data collection, or changes to the number of patients we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost of manufacturing our product candidates and any products we commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, and distribution costs, and any discounts or rebates to channel to obtain access;
- the cost of building a sales force in anticipation of product commercialization;
- our ability to establish and maintain strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements that we may enter into;
- the timing and amount of milestone payments due to AstraZeneca, Hengrui, or any future collaboration or licensing partners upon the achievement of negotiated milestones;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio; and
- the timing, receipt, and amount of sales of any future approved products, if any.

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

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

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

- delays in the commencement, enrollment, and the timing of clinical testing for our product candidates, especially in light of the COVID-19 pandemic;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development, or failure to obtain such approvals;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on U.S. FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies, which may include obligations to make significant upfront and milestone payments;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- the willingness of patients to pay out-of-pocket for our product candidates, if approved, in the absence of health insurance coverage or sufficient reimbursement;
- our dependency on Contract Research Organizations (CROs) and third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing, and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates both within and outside of the United States;
- our ability to establish and maintain collaborations, licensing, or other arrangements with respect to our product candidates;
- our ability to maintain and enforce our intellectual property position;
- costs related to and outcomes of potential litigation or other disputes in respect of our product candidates and our business;

- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

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

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

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and there can be no assurance as to its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this Quarterly Report on Form 10-Q. If this third-party or internally generated data prove to be inaccurate or we make errors in our assumptions based on that data, our actual market may be more limited than our estimates. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business. The estimates of our market opportunities included in this Quarterly Report on Form 10-Q should not be taken as indicative of our ability to grow our business.

Risks Related to Development and Commercialization

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

We currently have no products that are approved for commercial sale. Our current portfolio includes our lead product candidate roflumilast cream, a potent PDE4 inhibitor topical cream for the treatment of plaque psoriasis and atopic dermatitis, and our additional product candidates roflumilast foam, a topical foam formulation of roflumilast for the treatment of scalp psoriasis and seborrheic dermatitis, ARQ-252, a potent and highly selective topical JAK1 inhibitor for the treatment of chronic hand eczema and vitiligo, and ARQ-255, a potential topical treatment for alopecia areata. We currently do not have drug discovery efforts, and we have no intention to develop these. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval, and commercialization of our current product candidates. We expect to conduct most of our clinical trials in the United States and Canada, with currently limited plans for clinical trials in Australia, the Caribbean, and the EU. We currently anticipate seeking regulatory approvals in the United States and Canada, but may in the future be subject to additional foreign regulatory authorities and may out-license our product candidates or approved products, if any, in additional foreign markets. In the future, we may also become dependent on other product candidates that we may develop, acquire, or in-license. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate, particularly as a result of the impact of the COVID-19 pandemic, and will depend substantially upon the performance of third-party contractors;

- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our lead product candidates or any future product candidates or approved products, if any;
- the willingness of physicians and patients to utilize or adopt our product candidates;
- the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates to remain in good standing with relevant regulatory authorities and to develop, validate, and maintain commercially viable manufacturing processes that are compliant with cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale, and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, payors, and patients of the benefits, safety, and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges, or intellectual property infringement claims.

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of

testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, our Phase 2 proof of concept study in atopic dermatitis had a limited number of patients and did not reach statistical significance for the primary endpoint of absolute change in Eczema and Severity Index (EASI). However, this study did provide evidence that roflumilast cream could provide symptomatic improvement, with statistically significant difference from vehicle on several key secondary endpoints, and a favorable tolerability profile in adults with atopic dermatitis and, following an End of Phase 2 meeting with the FDA in September 2020, we omitted our previously planned Phase 2b study in that indication and recently initiated Phase 3 clinical trials. Additionally, our Phase 1/2b clinical study of ARQ-252 for the treatment of chronic hand eczema did not meet its primary end point of IGA clear or almost clear at week 12. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

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

- clinical site closures, delays to patient enrollment, subjects discontinuing treatment or follow-up visits, issues with data collection, or changes to trial protocols as a result of the COVID-19 pandemic;
- regulators or independent institutional review boards (IRBs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials, or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or IRBs to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

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

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

to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly.

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

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

We currently have no products approved for sale; we are currently preparing regulatory submissions for our lead product candidate, topical roflumilast cream, and our other product candidates remain in clinical development. Significant risk remains and we cannot provide assurance that they will obtain regulatory approval for commercialization as expected, or at all. The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions, including pricing approval in the EU.

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

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

may be, require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;

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

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

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could

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

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

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

The use of patient reported outcome instruments in our Phase 3 clinical trials of roflumilast cream and the inclusion of such data in the product labeling will depend on, but is not limited to, the FDA's review of the following:

- the relevance and importance of the concept(s) of interest to the target patient population;
- the strengths and limitations of the instrument within the given context of use;
- the design and conduct of the trials;
- the adequacy of the submitted data, for example, rigorous data collection and methods to handle missing data; and
- the magnitude of the statistically significant treatment effect should be meaningful to patients.

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

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

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

Patient enrollment is affected by other factors including:

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

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

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

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

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

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

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

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

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

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 limited experience doing 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 3 studies and three Phase 2 studies in plaque psoriasis with roflumilast cream, a Phase 2 study in atopic dermatitis with roflumilast cream, and two Phase 2 studies in seborrheic dermatitis and scalp psoriasis with roflumilast foam. We have also recently initiated pivotal Phase 3 clinical trials of roflumilast cream for 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. While the FDA encouraged us at our atopic dermatitis End of Phase 2 meeting to generate additional clinical data in adolescents and adults on the two roflumilast cream doses studied in our Phase 2 study, they also did not raise objections to us proceeding into Phase 3. If the FDA does not accept our applications or issue marketing authorizations for our product candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA for any other applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Additionally, similar risks could apply to receipt of marketing authorizations by comparable regulatory authorities in foreign jurisdictions.

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

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

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

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

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

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

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

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

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

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

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

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

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

To achieve commercial success for any product for which we obtain marketing approval, we will need to build a significantly more robust sales and marketing organization. We currently have limited infrastructure for the sales, marketing, or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

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

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

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

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

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

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

For example, upon regulatory approval from the FDA to commercialize roflumilast cream in the United States, but prior to commencement of commercialization or sales of roflumilast cream, we will be required to make certain milestone payments to AstraZeneca. We paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product (as defined below). We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specified regulatory approval milestones with respect to products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, AZ-Licensed Products, and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country.

In connection with the exercise of our exclusive option with Hengrui in December 2019, we made a $1.5 million cash payment and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, we have agreed to make cash payments of up to an aggregate of $20.5 million upon our achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional $200.0 million in sales-based milestones based on achieving certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products we commercialize under the agreement, we will pay tiered royalties to Hengrui on net sales of each licensed product by us, or our affiliates, or our sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the later of (1) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, we are obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income we receive from sublicensees of our rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

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

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

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

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

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

For psoriasis, our primary competitors include injected biologic therapies such as Humira, marketed by AbbVie Inc. and Eisai Co., Ltd., and Enbrel, marketed by Amgen Inc. and Pfizer Inc.; non-injectable systemic therapies used to treat plaque psoriasis such as Otezla, marketed by Amgen Inc.; topical therapies such as branded and generic versions of clobetasol, such as Clobex, marketed by Galderma Laboratories, LP, generic versions of calcipotriene and the combination of betamethasone dipropionate/calcipotriene; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat psoriasis and compete with roflumilast cream, including topical tapinarof, under development by Dermavant Sciences, Inc., deucravacitinib, an oral Tyk2 inhibitor under development by BMS, Inc., and PF-06700841, an oral Tyk2/JAK1 inhibitor under development by Pfizer, Inc.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., 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 Eli Lilly and Company.

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, 2021, we had 75 full-time employees. We will need to continue to expand our managerial, clinical, commercial, 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.

In order to effectively execute our growth strategy, we will need to identify, recruit, retain, incentivize and integrate additional employees in order to expand our ability to:

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

If we are unable to successfully identify, recruit, retain, incentivize and integrate additional employees and otherwise expand our managerial, operational, 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 efforts, but rather we intend to formulate, acquire or in-license rights to existing molecules to develop for dermatological indications. In addition, while we believe that our strategy allows us to move more rapidly through clinical development and at a potentially lower cost, we may be unable to progress product candidates more quickly or at a lower cost.

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

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

We may choose to focus our efforts and resources on 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 product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.

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

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

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

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

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

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 (Section 404) and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

During the course of our review and testing of our internal controls over financial reporting, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm to our business.

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

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

telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

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

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

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

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our

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

Risks Related to Our Reliance on Third Parties

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

We do not currently have the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. Instead, we currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. We have successfully manufactured and tested several batches of our topical roflumilast product candidates at our primary commercial contract manufacturing site at the initial commercial scale. However, as a late-stage company with no prior history of product sales or commercialization of products, representative batches of our product candidate received to date may not represent what will be required to meet our future commercial requirements or be manufactured at final commercial scale.

We and the manufacturers of our products rely on suppliers of raw materials used in the production of our products. Some of these materials are available from only one source. Although we have engaged in a commercial supply agreement and scale-up activities with our Drug Substance contract manufacturing organization (CMO), we have not yet finalized a Drug Product manufacturing agreement for the commercial supply of our product candidates. 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 are restored or alternative manufacturing facilities or sources of supply are procured. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturer's facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

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

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

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

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

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

Before beginning commercial manufacture of ARQ-151 roflumilast cream, ARQ-154 roflumilast foam, ARQ-252 or ARQ-255, the processes and systems used in their manufacture must be approved and each facility must have a compliance status that is acceptable to the FDA and other regulatory authorities. In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and foreign regulatory authorities before and after product approval. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to continue to pass or initially pass federal, state or international regulatory inspections. Furthermore, although we have very limited control over the day-to-day operations of our contract manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

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

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

We do not have the ability to independently conduct non-clinical studies and clinical trials. We rely on third parties, such as CROs, to conduct preclinical studies and clinical trials of roflumilast cream, roflumilast foam, ARQ-252 and ARQ-255. The third parties with whom we contract for execution of our preclinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. These third parties may also have relationships with other commercial entities, some of which may compete with us. In some cases, these third parties could terminate their agreements with us without cause. Furthermore, external events such as the COVID-19 pandemic could interfere with some operations of these CROs.

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

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

Risks Related to Intellectual Property

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

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

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

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current licensors, or any future licensors or licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted, and as a result may not be able to be enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how to our processes, methods, and know-how which we consider our trade secrets. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

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

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

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

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

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;

- for some product candidates, we expect that composition of matter patent protection for the active pharmaceutical ingredient will not be available at the time we expect to commercialize, and we will therefore need to rely on formulation, method of use and other forms of claims for patent protection;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. Our issued U.S. patents relating to roflumilast cream and roflumilast foam with claims directed to, among other things, formulating roflumilast in combination with hexylene glycol 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 PTE is granted. Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

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

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

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

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

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

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

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

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

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

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

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

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, product candidates and our target indications. Our issued U.S. patents, with claims directed to roflumilast formulations with reduced crystal growth, encompassing roflumilast cream, 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 (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications.

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

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

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

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

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

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

We have not yet received regulatory approval of our commercial tradename and registered trademarks for a commercial trade name for our lead candidates in the United States or foreign jurisdictions and failure to secure such approval in a timely fashion could adversely affect our business.

We have 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 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.

Risks Related to Government Regulation

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

Any regulatory approvals or other marketing authorizations we obtain for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or the conditions of approval or marketing authorization, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our drug product candidates, such as roflumilast cream, roflumilast foam, ARQ-252 and ARQ-255, which could include requirements for a medication guide, physician communication plans or additional ETASU, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority authorizes our product candidates for marketing, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

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

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. The policies of the FDA and of other regulatory authorities may change and additional governmental regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, certain policies of the new U.S. administration may impact our business and industry. Namely, the previous U.S. administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how or whether these executive actions, including the Executive Orders, will be implemented, or whether they will be rescinded or replaced by the new U.S. administration. Certain policies of U.S. presidential administrations may impact our business and industry, and changing presidential administrations may result in the issuance of Executive Orders that could impact our business, regulatory environment and industry. It is difficult to predict how such requirements, Executive Orders and policies will be implemented.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

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

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

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, the ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, manufacturers will also be required to report payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives during the previous year;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information;

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

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

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

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

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

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

regulatory burdens and operating costs. Among the provisions of the ACA of importance to our potential product candidates are the following:

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021; the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years; and the Medicare Access and CHIP Reauthorization Act of 2015, which, among other things, ended the use of the sustainable growth rate formula and provides for a 0.5% update to physician payment rates for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products.

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

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

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

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

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

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

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain

jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act (CCPA) on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

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

Risks Related to Our Common Stock

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

We qualify as an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including certain reduced financial statement reporting obligations, reduced disclosure obligations about our executive compensation arrangements, exemptions from the requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements and exemption from the auditor's attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." 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 of 1933, as amended, or the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

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

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

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

On May 6, 2021, we entered into a sales agreement, or Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $100,000,000, through an at-the-market equity offering program under which Cowen will act as our sales agent. During the three months ended March 31, 2021, we did not issue or sell any shares of our common stock through our ATM Offering Program. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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, 2021, our executive officers, directors and their respective affiliates beneficially owned approximately 47% 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 25.8 million shares of our common stock (including 1.4 million shares issued and sold pursuant to the private placement of shares in connection with our follow-on financing) have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

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

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. We have net operating loss (NOL) carryforwards available to reduce future taxable income, if any, for federal, California and other state income tax purposes. If not utilized, state NOL carryforwards will expire beginning in 2030. A small amount of our federal NOL that was originated before the 2018 tax year will expire beginning in 2036. Under the Tax Act and Jobs Act of 2017, the remaining amount of our federal NOL carryforwards generated after December 31, 2017 will carryforward indefinitely. Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership by certain stockholders over a three year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. A formal study has not been completed to determine if a change in ownership, as defined by Section 382, has occurred. We believe that we may undergo an “ownership change” limitation as a result of our IPO (some of which shifts are outside of our control). We may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

Our restated certificate of incorporation and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

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

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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

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

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

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

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

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

General Risk Factors

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

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

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

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

- limited daily trading volume resulting in the lack of a liquid market;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- regulatory, legal or political developments in the United States and foreign countries;
- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;
- the execution of our partnering and manufacturing arrangements;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the success of, and fluctuations in, the commercial sales any product candidates approved for commercialization in the future;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole, including as a result of market volatility related to global health concerns and, in particular, the extreme volatility experienced during the ongoing COVID-19 pandemic;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;

- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- FDA or foreign regulatory actions affecting us or our industry;
- changes in the structure of healthcare payment systems;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;
- the size of our market float;
- the expiration of market standoff or contractual lock-up agreements and future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- changes in accounting principles;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed in this Annual Report on Form 10-K.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Due to the COVID-19 outbreak, there has been significant stock market exchange volatility, including temporary trading halts. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

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

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We only recently completed our IPO and just recently obtained research coverage by securities and industry analysts. If only a limited number of securities or industry analysts commence coverage of us or the few analysts that have initiated coverage, drop coverage, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

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

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

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

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

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

If a natural disaster, power outage or other event occurred, including an epidemic, pandemic or contagious disease outbreak such as COVID-19 that disrupted operations, we may experience difficulties in operating our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

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

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

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

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

None.

Use of Proceeds

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

Issuer Purchases of Equity Securities

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

None.

Item 5. OTHER INFORMATION

Effective on February 8, 2021, we entered into an Exclusive Distribution Agreement (the “Distribution Agreement”) with Cardinal Health 105, Inc. (“Cardinal Health”) pursuant to which Cardinal Health will act as our exclusive third-party logistics distribution agent for commercial sales of pharmaceutical products that we manufacture or market. Under the Distribution Agreement, we have agreed to pay to Cardinal Health certain one-time and periodic fees for, among other things, supply, storage and warehousing operations, customer service and account management fees in connection with the exclusive distribution arrangement. The initial term of the Distribution Agreement is three years following the first shipment of an FDA approved product and shall automatically renew for additional one year terms unless written notice of termination is given by either party at least terminated by either party with 90 days’ notice prior to the end of the then current term. We may also terminate the Distribution Agreement during the initial three year term upon 180 days’ notice, provided that we pay a termination fee equal to a percentage of the remaining fees under the Distribution Agreement determined by the timing of such termination. The Distribution Agreement also contains customary representations and warranties, covenants, confidentiality provisions, and indemnification and limitations of liability provisions in favor of either party.

On May 6, 2021, we entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which we may from time to time issue and sell shares of its common stock through at-the-market ("ATM") offerings for an aggregate offering price of up to $100.0 million. Cowen will act as our sales agent for the ATM program. The issuance and sale of shares of common stock by us pursuant to the Sales Agreement are deemed an “at-the-market” offering under the Securities Act of 1933, as amended. Cowen is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold through Cowen under the Sales Agreement. The ATM program has been registered under the Securities Act pursuant to the Company's shelf registration statement on Form S-3, as amended (Registration No. 333-252612), as supplemented by the Prospectus Supplement dated May 6, 2021 relating to the sale of shares of our common stock. The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which was filed hereto as Exhibit 10.3 and is incorporated by reference herein. A copy of the opinion of Latham & Watkins LLP relating to the validity of the securities to be issued pursuant to the Sales Agreement is filed hereto as Exhibit 5.1.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document	Incorporated by Reference Form	Date	Number	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation.	10-Q	5/12/20	3.1	
3.2	Restated Bylaws.	10-Q	5/12/20	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	1/21/20	4.1	
4.2†	Amended and Restated Investors’ Rights Agreement, dated October 8, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	1/21/20	4.2	

4.3	Description of Arcutis Biotherapeutics' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	3/19/20	4.3	
5.1	Opinion of Latham & Watkins LLP				X
10.1†	Exclusive Distribution Agreement, dated February 8, 2021, by and between the Registrant and Cardinal Health 105, Inc.				X
10.2	Severance & Change in Control Agreement, by and between the Registrant and Scott L. Burrows				X
10.3	Sales Agreement, dated May 6, 2021, by and between the Registrant and Cowen and Company, LLC				X
23.1	Consent of Latham & Watkins LLP (included in Exhibit 5.1)				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

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

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the 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 06, 2021

By: /s/ Todd Franklin Watanabe

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

Date: May 06, 2021

By: /s/ Scott L. Burrows

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

Exhibit 5.1

140 Scott Drive
Menlo Park, California 94025
Tel: +1.650.328.4600 Fax: +1.650.463.2600
www.lw.com

LATHAM & WATKINS LLP

May 6, 2021

Arcutis Biotherapeutics, Inc.
2945 Townsgate Road, Suite 110
Westlake Village, California 91361

Re: Registration Statement on Form S-3 (No. 333-252612)
Up to $100,000,000 shares of common stock, $0.0001 par value per share

Ladies and Gentlemen:

We have acted as special counsel to Arcutis Biotherapeutics, Inc., a Delaware corporation (the **"Company"**), in connection with the proposed issuance from time to time of shares of common stock of the Company, $0.0001 par value per share (the **"Common Stock"**), having an aggregate offering price of up to $100,000,000 (the **"Shares"**), by the Company pursuant to the Sales Agreement, dated May 6, 2021 (the **"Sales Agreement"**) between the Company and Cowen and Company, LLC. The Shares are included in a registration statement on Form S-3 under the Securities Act of 1933, as amended (the **"Act"**), filed with the Securities and Exchange Commission (the **"Commission"**) on February 1, 2021 (Registration No. 333-252612) (as amended, the **"Registration Statement"**) and are being offered pursuant to a base prospectus dated February 1, 2021 (the **"Base Prospectus"**) and a prospectus supplement dated May 6, 2021 filed with the Commission pursuant to Rule 424(b) under the Act (together with the Base Prospectus, the **"Prospectus"**).

This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

LATHAM & WATKINS LLP

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters. We are opining herein as to the General Corporation Law of the State of Delaware (the "**DGCL"**), and we express no opinion with respect to any other laws.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers, and have been issued by the Company against payment therefor (not less than par value) in the circumstances contemplated by the Sales Agreement, the issuance and sale of the Shares will have been duly authorized by all necessary corporate action of the Company, and the Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that (i) the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the DGCL and (ii) upon the issuance of any of the Shares, the total number of shares of Common Stock issued and outstanding will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under its Certificate of Incorporation.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Company's Current Quarterly Report on Form 10-Q for the three month period ended March 31, 2021 and to the reference to our firm in the Prospectus under the heading "Legal Matters." In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Latham & Watkins LLP

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

EXCLUSIVE DISTRIBUTION AGREEMENT

This Exclusive Distribution Agreement (the "**Agreement**") is made as of this 8th day of February, 2021 (the "**Effective Date**"), between Arcutis Biotherapeutics, Inc. a corporation with an address of 3027 Townsgate Road, Suite 300, Westlake Village, CA 91361 ("**Client**"), and Cardinal Health 105, Inc., an Ohio corporation, with a place of business at 501 Mason Road, Suite 200, La Vergne, Tennessee, 37086 ("**Cardinal Health**") each individually a ("**Party**") and collectively (the "**Parties**").

RECITALS

A. Client is, among other things, in the business of developing and marketing pharmaceutical products in the United States, its territories, possessions and commonwealths ("**Territory**").

B. Cardinal Health is, among other things, in the business of distributing pharmaceutical products to wholesalers, specialty distributors, physicians, clinics, hospitals, pharmacies, and other health care providers in the Territory, and of providing information systems and other services that support its clients' use of its distribution capabilities.

C. Client desires to engage Cardinal Health as its exclusive third-party logistics distribution agent for commercial sales of all pharmaceutical Products manufactured and/or marketed by Client in all formulations (collectively, "**Product**"), and to perform certain other services described in this Agreement, all upon the terms and conditions set forth in this Agreement.

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the Parties agree as follows:

ARTICLE 1
Appointment/Authorization

1.1 Appointment. Subject to the terms and conditions set forth in this Agreement, during the term of this Agreement, Client appoints Cardinal Health as its exclusive third-party logistics distribution agent and as an authorized distributor of record of Product in the Territory to Client's Customers, including, but not limited to, wholesalers, specialty distributors, physicians, clinics, hospitals, pharmacies and other health care providers in the Territory (collectively, "**Customers**").

1.2 Acceptance of Appointment. Subject to the terms and conditions set forth in this Agreement, Cardinal Health accepts the appointment to represent Client as its exclusive third- party logistics distribution agent and as an authorized distributor of record of Product to Customers in the Territory.

ARTICLE 2
Services

2.1 Services. Cardinal Health shall provide the services set forth in the Traditional 3PL Operating Guidelines ("**OPG**"), which include, without limitation, storage, distribution, returns, customer support, financial support, EDI and system access support ("**Services**"). The OPG shall be finalized and mutually agreed upon prior to the commercial launch of Product. Once finalized, a copy of the OPG shall be attached hereto as **Exhibit A** and incorporated by reference.

2.2 Traditional 3PL Operating Guidelines. The OPG may be amended from time to time upon the mutual written agreement of the Parties; provided, however, that any change, modification or amendment to the OPG may result in an increase in the Fees (as defined in Article 5).

2.3 Compliance to Traditional 3PL Operating Guidelines. Cardinal Health's services shall comply with the OPG for up to [***] of Client's Forecast (defined below). If (i) Client's shipments of Product to Cardinal Health or (ii) Client's Customers' Product orders exceed Client's Forecast by more than [***] ([***]), Cardinal Health shall use commercially reasonable efforts to meet the requirements of the OPG, provided however, that Client acknowledges tha t Cardinal Health may not be able to meet all guidelines relating to response and shipping times.

2.4 Product Returns. All Product returns shall be processed and handled by Cardinal Health in accordance with the OPG; and any customization or additional return services requested by Client shall be performed at an additional fee as agreed by the Parties.

2.5 Product Recalls. Client is solely responsible for all Product recalls, provided however that Cardinal Health shall be responsible for Product recalls to the extent arising from Cardinal Health's gross negligence or willful misconduct, subject to the terms of this Agreement. In the event Product is subject to recall, or Client, on its own initiative, recalls any Product, Cardinal Health shall provide assistance to Client as set forth in the OPG and as mutually agreed upon, provided that Client shall pay to Cardinal Health an amount equal to Cardinal Health's actual costs incurred with any such recall services. Such cost shall be in addition to the Fees described in Article 5 below.

ARTICLE 3
Product Supply/Client Responsibilities

3.1 Facility. Client shall deliver Product to Cardinal Health at Cardinal Health's facility located at 15 Ingram Boulevard, La Vergne, Tennessee 37086 and/or 501 Mason Road, Suite 200, La Vergne, Tennessee 37086, or to such other distribution facility as may be designated by Cardinal Health to Client in writing ("**3PL Facility**").

3.2 Delivery and Title. Client shall be responsible for delivery of Product to and from the 3PL Facility, including all costs, expenses and risk of loss associated with such delivery. Title to Product shall remain with Client at all times, even when Product is stored or warehoused at the 3PL Facility. Client shall at all times insure the Product for damage, loss, destruction, theft or any such other property damage ("**Loss**") as further set forth in Article 13 below. Except for Loss resulting solely from the gross negligence or willful misconduct of Cardinal Health, Client shall bear all risk of loss or damage with respect to the Product.

3.3 Forecast and Price List.

A. Forecast. Client shall provide Cardinal Health with a forecast of the volume of Product to be handled by Cardinal Health under this Agreement, not less often than semi-annually ("**Forecast**"). All forecasts, including the Forecast, are used for the express purpose of operational planning. In the event of a significant variance from the Forecast or a significant change in core business that could reasonably be expected to have a material effect upon the obligations of either Party hereunder, the Party so affected may notify the other Party that it wishes to negotiate an appropriate adjustment to the Fees. The Parties must meet within thirty (30) days of such notification to discuss the merits and implementation of any such adjustment and during such meeting, the Parties shall negotiate in good faith. If the Parties are unable to come to a resolution regarding any such adjustment, the Party originally proposing the adjustment may terminate this Agreement upon one hundred eighty days (180) prior written notice to the other Party.

B. Price List. Upon execution of this Agreement, Client shall deliver to Cardinal Health a customer list, which sets forth the Product prices (the "**Customer Price List**"). Client shall notify Cardinal Health of any change in the Customer Price List not less than seventy-two (72) hours prior to the effective date of any such change. Cardinal Health shall use commercially reasonably efforts to implement such price change in accordance with Client's instruction.

3.4 Shipment Inspection. Cardinal Health shall visually inspect each shipment of Product for external damage or loss in transit and notify Client of any such evident damage or loss as provided in the OPG.

ARTICLE 4
Information System Access

4.1 Access. During the Term of this Agreement and subject to the terms herein, Client may use password(s) and identification number(s) provided by Cardinal Health to remotely access Client's data maintained on Cardinal Health's web enabled Operating System Base and certain support services associated therewith, as further set forth in the OPG (collectively, the "**System**") provided that such access is used solely by Client's employees and for Client's own internal business purposes. Client shall use that access solely to access Client's data and shall not access or attempt to access any other data, systems or software. Client shall be responsible for all use of the passwords and identification elements and shall ensure that they are used solely to effect the limited access authorized herein. The limited license to access the System granted herein does not include the right to copy, download or otherwise use any software or non-Client data maintained on the System.

4.2 Fees. The System shall be made available to Client at the fees set forth in the Fee Schedule. If Cardinal Health agrees to perform any custom enhancements to the System requested by Client, such customization services shall be billed separately based on an hourly rate set forth in the Fee Schedule (as defined in Article 5) and prior to such performance, Cardinal Health shall notify Client of any related increase in the periodic Fees hereunder relative to the ongoing support of the customizations.

4.3 Security. During the term of this Agreement, Cardinal Health shall employ reasonable security measures and policies designed to safeguard the integrity, accessibility, and confidentiality of Client's data resident on the System and establish and maintain reasonable disaster and emergency recovery plans designed to minimize disruption from System operation interruptions. Such measures shall be no less secure than those utilized by Cardinal Health to protect its own confidential information.

4.4 Client Obligations. Client shall not reverse engineer, reverse assemble, decompile, create derivative works, modify, or otherwise attempt to derive the source code of any software on the System or copy, download, modify, or create derivative works of such software. Also, Client shall not permit access to the System or related documentation to any other person or entity. The System and all parts thereof, in all of their tangible and intangible manifestations, all existing or new enhancements, developments, derivative works, and other modifications to the System (or any part thereof), and all related proprietary rights, are and shall remain the exclusive property of Cardinal Health.

4.5 Disclaimer. **THE SYSTEM, THE SOFTWARE THEREON AND ANY RESULTS OBTAINED THEREFROM ARE PROVIDED ON AN "AS IS" BASIS, WITHOUT WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE. CARDINAL HEALTH MAKES NO REPRESENTATIONS OR WARRANTIES, AND HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, RELATING DIRECTLY OR INDIRECTLY TO THE SYSTEM OR ANY PART THEREOF INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE.**

4.6 System Availability. Cardinal Health shall use reasonable efforts to make the System available for access twenty-four (24) hours a day, seven (7) days a week absent scheduled and emergency maintenance periods.

4.7 Suspension of Access. Notwithstanding anything to the contrary, in the event of a breach of any term of this Agreement or a threatened breach of the System, each as determined in good faith, Cardinal Health may revoke or suspend any or all passwords and identification numbers provided to Client hereunder.

ARTICLE 5
PRICING AND PAYMENT TERMS

5.1 Fees. As compensation for the Services, Client shall pay to Cardinal Health the fees ("**Fees**") set forth on **Exhibit B** ("**Fee Schedule**") attached hereto and incorporated by reference.

5.2 Invoices. Cardinal Health shall issue an invoice to Client for the Services rendered under this Agreement or for any other amounts due on a monthly basis. Payment is due within thirty (30) days of the invoice date. If the invoice is not paid (except for amounts subject to a good faith dispute) within such thirty (30) day period, Cardinal Health may, at its option elect to (i) impose a service charge on unpaid amount (except for amounts subject to a good faith dispute) calculated at the rate of 1.5% per month (or the maximum rate permitted by law if such rate is less than 1.5% per month) until such amount is paid in full and/or (ii) suspend any further Services until such invoice is paid in full provided, however, that this provision shall not apply in the event any unpaid portion of the invoice is the subject of an unresolved good faith dispute. In the event of any good faith dispute with regard to an invoice, Client shall notify Cardinal Health of such dispute within thirty (30) days of the invoice date, and any undisputed portion of the invoice shall be paid as provided herein. The Parties will work together in good faith to resolve any dispute with respect to an invoice. Any amounts owed to Cardinal Health shall be paid within ten (10) days of resolution of such dispute.

5.3 Fee Adjustment.

A. The Fees shall be held firm for the first contract year. Thereafter, Cardinal Health will evaluate the fee schedule and may adjust the Fees not more often than once per contract year by no more than [***] ([***]).

B. Notwithstanding the terms set forth above in Section 5.3(A), if Cardinal Health can reasonably demonstrate that the costs for providing the Services have materially increased, or are likely to materially increase in the coming year due to the adoption of any applicable law or regulation (or any material change in the interpretation or administration thereof), or due to unforeseen circumstances beyond Cardinal Health's reasonable control, then upon notice from Cardinal Health, the Parties agree to meet in good faith and negotiate a mutually acceptable adjustment to the Fees.

5.4 Taxes. Client shall pay when due all sales, use, gross receipts, excise and personal property taxes associated with the Product (excluding any personal property tax associated with Cardinal Health's equipment used in connection with the Services), and other taxes now or hereafter imposed as a result of the transactions contemplated by this Agreement, none of which have been included in the fees payable to Cardinal Health under this Agreement; provided that the amounts payable by Client under this section shall not include taxes based on the net income of Cardinal Health.

ARTICLE 6
Term and Termination

6.1 Term. The Initial Term of this Agreement shall begin on the Effective Date and shall continue for a period of three (3) years following the first shipment of FDA-approved Product to a commercial customer ("**Initial Term**"), unless terminated earlier pursuant to this Agreement. Thereafter, this Agreement shall automatically renew for additional terms of one (1) year each (each, a "**Renewal Term**," and together with the Initial Term, the "**Term**"), unless written notice of termination is given by either Party at least ninety (90) days prior to the end of the Initial Term or any Renewal Term.

6.2 Termination

A. Client shall have the right to terminate this Agreement upon one hundred eighty (180) days' notice to Cardinal Health, provided that, if Client terminates this Agreement during the Initial Term per the terms of this section 6.2(A), such termination shall be effective only upon payment to Cardinal Health of all undisputed outstanding amounts and (a) [***] ([***]) of all remaining Fixed Fees set forth on the Fee Schedule for the remainder of the Initial Term if the Client so terminates within the first year after the Effective Date; (b) [***] ([***]) of all remaining Fixed Fees set forth on the Fee Schedule for the remainder of the Initial Term if the Client so terminates after the first year after the Effective Date but prior to end of the second year after the Effective Date; or (c) [***] ([***]) of all remaining Fixed Fees set forth on the Fee Schedule for the remainder of the Initial Term if the Client so terminates after the second year after the Effective Date but prior to end of the third year after the Effective Date (the "**Termination Fee**"). "**Fixed Fees**" shall mean the fees specified on the Fee Schedule to be paid monthly by Client to Cardinal Health that are not dependent on the quantity of Product handled by Cardinal Health.

B. Either Party shall have the right to immediately terminate this Agreement if:

(i) the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within thirty (30) days; or

(ii) the other Party materially breaches any of the provisions of this Agreement, and such breach is not cured within thirty (30) days after the giving of written notice; provided, however, that (i) in the case of a breach that cannot be cured within thirty (30) days, the Parties agree to meet in good faith and within thirty (30) days after the giving of written notice, formulate a mutually agreeable plan to cure such breach within a reasonable period of time, provided, however, if such breach is not cured within the agreed upon time, the non-breaching party may terminate immediately; and (ii) in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Cardinal Health may terminate this Agreement if such payment breach is not cured within ten (10) days following Cardinal Health's delivery of a written notice of non-payment to Client.

6.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination. Client shall pay Cardinal Health for all Services performed up to the date of termination plus any applicable Termination Fee as set forth in Section 6.2(A) above and shall reimburse Cardinal Health for all costs and expenses incurred, and all non-cancelable commitments made up to the date of termination, in the performance of Services. Upon termination or expiration of this Agreement, all Product shall be returned to Client or a designee of Client, at Client's sole cost and expense.

ARTICLE 7
REGULATORY

7.1 Audits. No more than [***] per calendar year, Client or its designee has the right during normal business hours [i.e., 8:00 a.m. to 5:00 p.m. local 3PL Facility time and not to exceed a total of eight (8) business hours], to conduct a complete quality audit upon [***] days prior written notice to Cardinal Health. If the timing of such audit falls during "quarter-end" or "year-end" then Cardinal Health will use best efforts to accommodate Client's request. Client shall have the right to conduct for cause audits immediately if necessary, to ensure Product safety or if otherwise necessary to implement or support a Product recall.

7.2 Compliance with Laws. Each Party shall conduct its activities in connection with this Agreement in compliance with all applicable United States laws, rules, regulations and guidelines.

ARTICLE 8
Representations and Warranties

8.1 Cardinal Health. Cardinal Health represents and warrants to Client that, unless otherwise agreed to by the Parties, Cardinal Health shall perform Services in accordance with this Agreement, the OPG, and applicable United States laws, rules, regulations and guidelines.

8.2 Client. Client represents, warrants and covenants to Cardinal Health that:

A. Product. The Product shall not be adulterated or misbranded as provided in the Food, Drug and Cosmetic Act, as amended from time to time;

B. Promotion. Client's activities relating to the promotion, sale and distribution of the Product shall comply with all applicable laws, rules, regulations and guidelines;

C. No Infringement. It has all necessary authority and right, title and interest in and to any intellectual property related to each Product or that is otherwise provided by Client under this Agreement;

D. Safe Handling Instructions. It has provided all safe handling instruction, health and environmental information and material safety data sheets applicable to the Product or to any materials supplied by Client in writing in sufficient time for review and training by Cardinal Health prior to delivery; and

8.3 Mutual. Each Party represents and warrants to the other Party that:

A. Existence and Power. Such Party (i) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (ii) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (iii) is in compliance with all requirements of applicable laws, except to the extent that any noncompliance would not materially adversely affect such Party's ability to perform its obligations under the Agreement;

B. Authorization and Enforcement of Obligations. Such Party (i) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

C. Execution and Delivery. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

D. No Consents. All necessary consents, approvals and authorizations of all regulatory authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and

E. No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable laws; and (ii) do not materially conflict with or constitute a material default or require any consent under, any contractual obligation of such Party.

8.4 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE 8 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 9
Trademarks

Neither Party shall have the right to use the name of the other Party or any Affiliate of the other Party, or the other Party's or such Affiliates' trademarks, service marks, logos, or other similar marks in any manner except with the prior written approval of that Party; provided that the foregoing shall not prohibit Cardinal Health's use of Client's names or marks in connection with the performance of the Services in a manner consistent with this Agreement. "**Affiliate**," as used in this Agreement, means any legal entity which, during the Term hereof, controls, is controlled by, or is under common control with, such Party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting interest of all equity interests of the other entity (or other such comparable ownership interest for an entity other than a corporation).

ARTICLE 10
Confidentiality AND NON-USE

10.1 Mutual Obligation. Cardinal Health and Client agree that they shall not use the other Party's Confidential Information (defined below) except as necessary for the receiving Party to perform its obligations under this Agreement or disclose the other Party's Confidential Information to any third party without the prior written consent of the other Party except as required by law, regulation or court or administrative order (including without limitation, as required by and/or in order to comply with the requirements of the Securities and Exchange Commission (SEC) or any other agency governing publicly traded companies, including in connection with Client's public filings); provided, however, that prior to making any such legally required disclosure, the Party making such disclosure shall give the other Party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information to any of its Affiliates that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this article, and (C) agree to be bound by the terms of this article.

10.2 Definition. As used in this Agreement, the term "**Confidential Information**" includes all such information furnished by Cardinal Health or Client, or any of their respective representatives or Affiliates, to the other or its representatives or Affiliates in connection with the services or performance of this Agreement, whether furnished before, on or after the date of this Agreement and furnished in any form, including but not limited to written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either Party, or any of their respective representatives, containing or based in whole or in part on any such information furnished by the other Party or its representatives. Confidential Information also includes the existence of this Agreement and its terms.

10.3 Exclusions. Notwithstanding Section 10.2, Confidential Information does not include information that (A) is or becomes generally available to the public other than as a result of a breach of this Agreement, or (B) is already known by the receiving Party at the time of disclosure as evidenced by the receiving Party's written records, or (C) becomes available to the receiving Party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (D) was or is independently developed by or for the receiving Party without reference to the Confidential Information, as evidenced by the receiving Party's written records.

10.4 No Implied License. The receiving Party shall obtain no right of any kind or license under any patent application or patent by reason of this Agreement. All Confidential Information shall remain the sole property of the Party disclosing such information or data.

10.5 Return of Confidential Information. Upon termination of this Agreement, the receiving Party shall, upon request, promptly return within thirty (30) days all such information, including any copies thereof, and cease its use or, at the request of the disclosing Party, shall promptly destroy the same and certify such destruction to the disclosing Party; except for a single copy thereof, which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement.

10.6 Survival. The Parties intend for this Article 10 to supersede that certain Confidentiality Agreement between the parties dated the 5th day of August, 2020. The obligations of this Article 10 shall terminate five (5) years from the expiration of this Agreement.

ARTICLE 11
Indemnification

11.1 Indemnification by Cardinal Health. Cardinal Health shall indemnify and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents ("**Client Indemnitees**") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorney' fees) in connection with any suit, demand or action by any third party ("**Liabilities**") arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement or (B) any negligence or willful misconduct by Cardinal Health, except to the extent that any of the foregoing arises out of or results from any Client Indemnitee's negligence, willful misconduct or breach of this Agreement.

11.2 Indemnification by Client. Client shall indemnify and hold harmless Cardinal Health, its Affiliates, and their respective directors, officers, employees and agents ("**Cardinal Health Indemnitees**") from and against all Liabilities arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement; (B) any manufacture, sale, promotion, distribution, shipping, use of or exposure to the Product or any materials supplied by Client, including, without limitation, product liability or strict liability; (C) Client's exercise of control over the Services to the extent that Client's instructions or directions violate applicable law; (D) any actual or alleged infringement or violation of any patent, trade secret, copyright, trademark or other proprietary rights concerning the Product or provided by Client; or (E) any negligence or willful misconduct by Client, except to the extent that any of the foregoing arises out of or results from any Cardinal Health Indemnitee's negligence, willful misconduct or breach of this Agreement.

11.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification: (A) promptly notifying the indemnifying Party of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure; (B) reasonably cooperating with the indemnifying Party in the defense of any such claim or liability (at the indemnifying Party's expense); and (C) not compromising or settling any claim or liability without prior written consent of the indemnifying Party.

ARTICLE 12
LimitationS of Liability

12.1 CARDINAL HEALTH'S TOTAL LIABILITY UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR TORT, INCLUDING, WITHOUT LIMITATION, ANY OF CARDINAL HEALTH'S INDEMNITY OR OTHER FINANCIAL OBLIGATIONS UNDER ARTICLE 11, SHALL NOT EXCEED TWO TIMES (2X) THE TOTAL FEES PAID BY CLIENT TO CARDINAL HEALTH FOR THE SERVICES WHICH WERE INVOLVED IN CAUSING ANY CLAIMS, DAMAGES, LOSSES, COSTS OR EXPENSES.

12.2 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITS OR DATA, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

12.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, THE LIMITATIONS IN THIS ARTICLE 12 SHALL NOT LIMIT CLIENT'S LIABILITY OR RESPONSIBILITY RELATING TO A BREACH OF ITS OBLIGATIONS UNDER ARTICLE 4 HEREIN.

ARTICLE 13
Insurance

13.1 Insurance Policies. During the term of this Agreement, Client shall obtain and maintain the following insurance with limits not less than those specified below:

A. Products and Completed Operations Liability Insurance covering the Products included in this Agreement with a limit of not less than $[***] per occurrence;

B. All-Risk Property Insurance, including transit coverage, in an amount equal to full replacement value covering Client's property while it is at the 3PL Facility or in transit to or from the 3PL Facility. Client's all-risk property insurance shall apply to all losses and be primary (with respect both to any insurance issued to Cardinal Health and to any deductible amount or

self-insured amount retained by Cardinal Health) except for losses resulting solely from the gross negligence or willful misconduct of Cardinal Health.

In the event that any of the required policies of insurance are written on a claims-made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than five (5) years following the termination or expiration of this Agreement.

13.2 Waiver. Client shall obtain a waiver from any insurance carrier with whom Client carries Property Insurance releasing its subrogation rights against Cardinal Health except for losses resulting solely from the gross negligence or willful misconduct of Cardinal Health. Client shall not seek reimbursement for any property claim, or portion thereof that is not fully recovered from Client's property insurance except for losses resulting solely from the gross negligence or willful misconduct of Cardinal Health.

13.3 Additional Insured Status. Cardinal Health, Inc., and its Affiliates shall be named as additional insureds under the Products and Completed Operations Liability insurance policies as respects the Products and completed operations outlined in this Agreement. Such insurance shall be primary (with respect both to any insurance issued to Cardinal Health and to any self-insured amount retained by Cardinal Health) with regard to Cardinal Health's liability for damage arising out of those products for which they have been added as additional insureds. Such additional insurance status shall continue during the term and, if the policies are written on a claims-made basis, shall continue for not less than five (5) years following termination or expiration of this Agreement.

13.4 Certificates. Client shall furnish certificates of insurance to Cardinal Health evidencing the required insurance and additional insured status as soon as practicable after the Effective Date and within thirty (30) days after renewal of such policies. Client will endeavor to provide thirty (30) days written notice of any cancellation prior to the policy(ies) expiration date(s). Each insurance policy that is required under this article shall be obtained from an insurance carrier with an A.M. Best rating of at least A-VII.

ARTICLE 14
NOTICES

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

To Client: Arcutis Biotherapeutics
3027 Townsgate Road, Suite 300
Westlake Village, CA 91361
Attn: VP of Market Access

With a copy to:
Arcutis Biotherapeutics
3027 Townsgate Road, Suite 300
Westlake Village, CA 91361
Attn: General Counsel

To Cardinal Health: Cardinal Health 105, Inc.
Third-Party Logistics Services
501 Mason Road, Suite 200
La Vergne, TN 37086
Attn: VP, Operations

With a copy to: Cardinal Health, Inc.
7000 Cardinal Place
Dublin, Ohio 43017
Attn: Associate General Counsel
Facsimile: [***]

ARTICLE 15
Miscellaneous

15.1 Entire Agreement; Amendments. This Agreement, the attachments and any amendments thereto constitute the entire understanding between the Parties and supersede any contracts, agreements or understanding (oral or written) of the Parties with respect to the subject matter hereof. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise provided in this Agreement.

15.2 Captions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement

15.3 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

15.4 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances shall not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

15.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement shall continue in full force and effect.

15.6 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party shall incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or shall be construed as creating between the Parties the relationship of joint venturers, co-partners, employer/employee or principal and agent.

15.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning company to which this Agreement relates.

15.8 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Tennessee, excluding its conflicts of law provisions. **The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.**

15.9 Dispute Resolution. If any dispute, controversy or disagreement arises between the Parties ("**Dispute**"), such Dispute shall be presented to the respective presidents or senior executives of Cardinal Health and Client for their consideration and resolution. If such Parties cannot reach a resolution of the Dispute within sixty (60) days, either Party may submit the Dispute to a court of appropriate jurisdiction.

15.10 Prevailing Party. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party shall be entitled to its reasonable attorney's fees and costs in such proceeding.

15.11 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

15.12 Publicity. Neither Party shall make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under applicable law or by any governmental agency (including without limitation, as required by and/or in order to comply with the requirements of the Securities and Exchange Commission (SEC) or any other agency governing publicly traded companies, including in connection with Client's public filings), in which case the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

15.13 Setoff. Without limiting Cardinal Health's rights under law or in equity, Cardinal Health and its Affiliates, parent or related entities, collectively or individually, may exercise a right of set-off against any and all amounts due to Cardinal Health from Client that are at least thirty (30) days past due after providing Client with not less than fifteen (15) business days' prior written notice (specifying the supporting details for such amount due). For purposes of this section, Cardinal Health, its Affiliates, parent or related entities shall be deemed to be a single creditor.

15.14 Survival. The rights and obligations of the Parties shall continue under Articles 10 (Confidentiality and Non-Use), to the extent expressly stated therein, 11 (Indemnification), 12 (Limitations of Liability), 13 (Insurance), to the extent expressly stated therein, 14 (Notice) and 15 (Miscellaneous) and Section 6.4 (Effect of Termination), notwithstanding expiration or termination of this Agreement.

15.15 Force Majeure. Except as to payments required under this Agreement, neither Party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such Party's performance hereunder if such default or delay is caused by events beyond such Party's reasonable control including, but not limited to, acts of God, regulation or law or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or storm, labor disturbances, epidemic, or failure of suppliers, public utilities or common carriers; provided however, that the Party seeking relief hereunder shall immediately notify the other Party of such cause(s) beyond such Party's reasonable control. The Party that may invoke this section shall use all reasonable endeavors to reinstate its ongoing obligations to the other. If the cause(s) shall continue unabated for one hundred eighty (180) days, then both Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from this force majeure.

[Signature Page to Exclusive Distribution Agreement Follows]

IN WITNESS WHEREOF, the undersigned have caused their duly authorized representative to execute this Agreement effective as of the date first written above.

CARDINAL HEALTH 105, INC. **Arcutis Biotherapeutics, Inc.**

By: /s/ Joel Waymen By: /s/ Frank Watanabe

Joel Wayment
VP, Operations

Frank Watanabe
President and CEO

Date: 2/18/2021 Date: 2/18/2021

[Signature Page to Exclusive Distribution Agreement]

ARCUTIS BIOTHERAPEUTICS, INC. SEVERANCE & CHANGE IN CONTROL AGREEMENT

This Severance & Change in Control Agreement (the "**Agreement**"), is entered into by and between Scott L. Burrows (the "**Executive**") and Arcutis Biotherapeutics, Inc., a Delaware company (the "**Company**"), and is effective as of the date that this Agreement is signed by both parties (the "**Effective Date**"). This Agreement supersedes the Severance & Change in Control Agreement previously entered into by and between the Executive and the Company which was effective as of the first date on which the registration statement on Form S-1 for the initial public offering of the Company's Common Stock was declared effective by the United States Securities and Exchange Commission or, if later, the date that the prior agreement was signed.

1. **TERM OF AGREEMENT.**

This Agreement shall terminate on the earlier of (i) the date Executive's employment with the Company terminates for a reason other than a Qualifying Termination, or (ii) the date the Company has met all of its obligations under this Agreement following a Qualifying Termination (the "**Expiration Date**").

2. **SEVERANCE BENEFIT.**

Executive's receipt of any payments or benefits under Section 2 is subject to (I) Executive's continued compliance with any confidential information agreement or restrictive covenant agreement by and between Executive and the Company, including, without limitation that certain Employee Invention Assignment and Confidentiality Agreement by and between Executive and the Company and any restrictive covenants contained in any employment agreement or offer letter agreement by and between Executive and the Company, and (II) Executive's delivery to the Company of a general release (in a form prescribed by the Company) of all known and unknown claims that he or she may then have against the Company or persons affiliated with the Company (the "**Release**"), and satisfaction of all conditions to make the Release effective, within sixty (60) days (or such shorter period required by the Company) (the "**Release Period**") following Executive's Qualifying Termination, notwithstanding any other provision of this Agreement. In no event will any payment or benefits under Section 2 be paid or provided until the Release becomes effective and irrevocable or in the event Executive violates any agreement set forth in subsection (I) in the foregoing sentence.

(a) **Qualifying Termination Outside of a Change in Control Period.** If the Executive is subject to a Qualifying Termination outside of a Change in Control Period, the Executive shall be entitled to the following:

(i) Severance Payments. The Company shall pay Executive nine (9) months of Executive's base salary at the rate in effect immediately prior to the Qualifying Termination (the "**Severance**"). The Severance shall be paid out in substantially equal installments in accordance with the Company's payroll practice over the total number of months of Severance commencing the first payroll period more than 60 days after the Qualifying Termination, subject to the Release becoming effective prior to such time (with the first payment to include all amounts that otherwise would have been paid through such date). Solely for purposes of Section 409A of the Code, each installment payment is considered a separate payment.

(ii) Health Care Benefit. If the Executive elects to continue his or her health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act ("**COBRA**") following

the termination of Executive's employment, then the Company shall pay, or reimburse, the Executive's monthly premium for Executive and his or her covered dependents under COBRA until the earliest of (A) nine (9) months, (B) the date when the Executive receives similar coverage with a new employer or (C) the expiration of the Executive's continuation coverage under COBRA; provided that on the first date such amounts become payable as described above, the Company shall pay to Executive a lump sum cash payment equal to the monthly premiums that would have been paid on behalf of Executive had such payments commenced on the date of the Qualifying Termination. Notwithstanding the foregoing, the Company may elect that, in lieu of paying or reimbursing the premiums, the Company shall instead provide Executive with a monthly cash payment equal to the amount the Company would have otherwise paid pursuant to this Section 2(a)(ii), less applicable tax withholdings.

(b) **Qualifying Termination During a Change in Control Period.** If Executive is subject to a Qualifying Termination during a Change in Control Period, Executive shall be entitled to the following:

i. Severance Payments. The Company shall pay Executive twelve (12) months of Executive's base salary at the rate in effect immediately prior to the Qualifying Termination or the Change in Control, whichever is greater, and 1.0 times Executive's annual bonus for the then-current fiscal year based on 100% of target performance of any applicable performance objectives (together, the "**CIC Severance**"). The CIC Severance shall be paid out in substantially equal installments in accordance with the Company's payroll practice over the total number of months of CIC Severance commencing the first payroll period more than 60 days after the Qualifying Termination, subject to the Release becoming effective prior to such time (with the first payment to include all amounts that otherwise would have been paid through such date). Solely for purposes of Section 409A of the Code, each installment payment is considered a separate payment.

ii. Health Care Benefit. If the Executive elects to continue his or her health insurance coverage under COBRA following the termination of Executive's employment, then the Company shall pay, or reimburse, the Executive's monthly premium for Executive and his or her covered dependents under COBRA until the earliest of (A) twelve (12) months, (B) the date when the Executive receives similar coverage with a new employer or (C) the expiration of the Executive's continuation coverage under COBRA; provided that on the first date such amounts become payable as described above, the Company shall pay to Executive a lump sum cash payment equal to the monthly premiums that would have been paid on behalf of Executive had such payments commenced on the date of the Qualifying Termination. Notwithstanding the foregoing, the Company may elect that, in lieu of paying or reimbursing the premiums, the Company shall instead provide Executive with a monthly cash payment equal to the amount the Company would have otherwise paid pursuant to this Section 2(b)(ii), less applicable tax withholdings.

iii. Equity. Each of Executive's then-outstanding unvested Equity Awards, other than Performance Awards (defined below), shall accelerate and become vested and exercisable or settleable with respect to 100% of the then-unvested shares subject to the Equity Awards. With respect to awards that would otherwise vest only upon satisfaction of performance criteria ("**Performance Awards**"), the grant agreement for the Performance Award may provide for alternative treatment upon a Qualifying Termination and, absent any such treatment in such grant agreement, the vesting acceleration provided for herein shall be deemed to have been met based on the achievement of the Performance Award at the greater of "at target" or, if determinable, actual performance. The accelerated vesting described above shall be effective as of the later of (x) the fifth (5th) business day following expiration of the Release Period, and (y) the closing of the Change in Control; provided, that if (1) the Company terminates Executive's employment for any reason other than Cause before a Change in Control, or (2) Executive

voluntarily resigns his or her employment for Good Reason before a Change in Control, then any unvested Equity Awards that would otherwise forfeit upon such termination shall remain outstanding and eligible to vest for three (3) months following such termination (provided that in no event will the Equity Awards remain outstanding beyond

the expiration of the Equity Award's maximum term) to permit the acceleration described above. For the avoidance of doubt, upon such termination before a Change in Control, any unvested Equity Awards will not vest in the ordinary course and will only be eligible to vest in the event that a Change in Control is completed within such three (3) month period. In the event that a Change in Control is not completed during such three (3) month period, any unvested portion of the Equity Awards will be automatically and permanently forfeited without having vested effective three (3) months following such termination.

iv. **Non-Assumption of Equity Awards.** Notwithstanding anything to the contrary, if, in connection with a Change in Control, the successor or acquiring corporation (if any) of the Company refuses to assume, convert, replace, or substitute Executive's unvested Equity Awards, then notwithstanding any other provision in this Agreement, or any Equity Award Agreement to the contrary, each of Executive's then-outstanding and unvested Equity Awards, other than Performance Awards, that are not assumed, converted, replaced, or substituted in such Change in Control shall accelerate and become vested and exercisable as to 100% of the then-unvested shares subject to the Equity Awards effective immediately prior to the Change in Control and terminate to the extent not exercised (as applicable) upon the Change in Control. With respect to Performance Awards, the vesting for such Performance Awards will accelerate as set forth in the terms of the applicable performance-based Equity Award agreement; and, absent any such treatment in such grant agreement, the vesting acceleration provided for herein shall be deemed to have been met based on the achievement of the Performance Award at the greater of "at target" or, if determinable, actual performance.

(c) **Accrued Compensation and Benefits.** Notwithstanding anything to the contrary in Section 2 above, in connection with any termination of employment, the Company shall pay Executive's earned but unpaid base salary and other vested but unpaid cash entitlements, including the amount of any bonus earned and payable from a prior year which remains unpaid by the Company as of the date of the termination of employment determined in accordance with customary practice or as required by applicable law and unreimbursed documented business expenses incurred by Executive through and including the date of termination (collectively "**Accrued Compensation and Expenses**"). Any Accrued Compensation and Expenses to which Executive is entitled shall be paid to Executive in cash as soon as administratively practicable, in accordance with the Company's standard payroll schedule and procedures, after the termination, and, in any event, no later than two and one-half (2-1/2) months after the end of the taxable year of Executive in which the termination occurs or at such earlier time as may be required by applicable law.

3. **COMPANY POLICIES.** Executive will be bound by and comply fully with that certain Employee Invention Assignment and Confidentiality Agreement by and between the Company and Executive and the Company's insider trading policy, code of conduct, and any other policies and programs adopted by the Company regulating the behavior of its employees, as such policies and programs may be amended from time to time to the extent the same are not inconsistent with this Agreement.

4. **DEFINITIONS.**

(a) "**Board**" means the Company's Board of Directors.

(b) "**Cause**" means the occurrence of any of the following events, as determined by the Company and/or the Board in its and/or their sole and absolute discretion: (i) Executive engaging in any act of fraud, embezzlement or material act of dishonesty or misrepresentation with respect to the Company;
(ii) Executive's violation of any federal or state law or regulation applicable to the business of the Company or its affiliates; (iii) Executive's material breach of any confidentiality agreement or assignment agreement between Executive and the Company (or any affiliate of the Company); (iv) Executive's conviction of or plea of *nolo contendere* to a felony involving moral turpitude; (v) Executive's unauthorized use or disclosure of confidential information or trade secrets of the Company (or any parent, subsidiary or affiliate); (vi) any intentional misconduct by Executive adversely affecting the business or affairs of the Company (or any parent, subsidiary or affiliate) in any material manner; (vii) Executive has committed any breach of fiduciary or statutory duty that results in (or would reasonably be expected to result in) material harm to the Company; (viii) Executive has breached any material term or condition of this Agreement or any other material agreement with or material policy of the Company; (ix) Executive's willful and repeated failure to perform in any material respect Executive's duties hereunder after fifteen (15) days' notice and an opportunity to cure such failure and a reasonable opportunity to present to the Board Executive's position regarding any dispute relating to the existence of such failure (other than on account of disability); or (x) Executive's failure to attempt in good faith to implement a clear and reasonable directive from the CEO or CFO (or the Board).

provided; however that the action or conduct described in clause (viii) above will constitute "Cause" only if such action or conduct continues after the Company has provided Executive with written notice thereof and ten (10) business days to cure the same if such action or conduct is curable. The determination as to the existence of grounds for Executive's termination for Cause shall be made in good faith by the Company or the Board and shall be final and binding on Executive.

(c) "**Code**" means the Internal Revenue Code of 1986, as amended.

(d) "**Change in Control**" means the occurrence of any of the following events: (i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then outstanding voting securities; (ii) the consummation of the sale or disposition by the Company of all or substantially all of the Company's assets; or (iii) the consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation.

(e) "**Change in Control Period**" means the period (i) within eighteen (18) months following the closing of a Change in Control, or (ii) within three (3) months preceding the closing of a Change in Control.

(f) "**Equity Awards**" means all awards for the Company common stock granted to Executive, including but not limited to options, stock bonus awards, restricted stock, restricted stock units, and stock appreciation rights.

(g) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

(h) "**Good Reason**" means the occurrence of any of the following events or conditions, without Executive's express written consent: (i) a material diminution of Executive's base salary or target annual performance bonus; (ii) a material diminution in Executive's authority, duties or responsibilities; or (iii) any requirement by the Company that Executive's principal place of employment be relocated to a location more than fifty (50) miles from Executive's principal place of employment prior to such change, which relocation materially increases Executive's commuting distance.

A termination of employment for Good Reason shall be effectuated by giving the Company written notice ("**Notice of Termination for Good Reason**"), setting forth in reasonable detail, the specific conduct of the Company that constitutes Good Reason and the specific provision(s) of this Notice on which Executive is

relying. Notice of Termination for Good Reason must be provided within ninety (90) days of the condition first arising. The Company will have an opportunity to cure such conduct constituting Good Reason within thirty (30) days of receiving such Notice of Termination for Good Reason. If the Company does not cure such conduct within such thirty (30) day period, a termination of employment for Good Reason shall be effective on the thirty-first (31st) day following the date when the Notice of Termination for Good Reason is received by the Company.

(h) "**Qualifying Termination**" means a Separation resulting from (x) the Company terminating Executive's employment for any reason other than Cause or (y) Executive voluntarily resigning his or her employment for Good Reason.

(j) "**Separation**" means a "separation from service," as defined in the regulations under Section 409A of the Code, if required by Section 409A of the Code.

5. **SUCCESSORS.**

(a) **Company's Successors**. The Company shall require any successor (whether direct or indirect and whether by purchase, merger, consolidation, liquidation, or otherwise) to all or substantially all of the Company's business and/or assets to assume this Agreement and to agree expressly to perform this Agreement in the same manner and to the same extent as the Company would be required to perform it in the absence of a succession. For all purposes under this Agreement, the term "**Company**" shall include any successor to the Company's business and/or assets or which becomes bound by this Agreement by operation of law.

(b) **Executive's Successors**. This Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees, and legatees.

6. **GOLDEN PARACHUTE TAXES.**

(a) **Best After-Tax Result**. In the event that any payment or benefit received or to be received by Executive pursuant to this Agreement or otherwise ("**Payments**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this subsection (a), be subject to the excise tax imposed by Section 4999 of the Code, any successor provisions, or any comparable federal, state, local or foreign excise tax ("**Excise Tax**"), then, subject to the provisions of Section 6(b) hereof, such Payments shall be either (x) provided in full pursuant to the terms of this Agreement or any other applicable agreement, or (y) provided as to such lesser extent which would result in no portion of such Payments being subject to the Excise Tax ("**Reduced Amount**"), whichever of the foregoing amounts, taking into account the applicable federal, state, local, and foreign income, employment and other taxes and the Excise Tax (including, without limitation, any interest or penalties on such taxes), results in the receipt by Executive, on an after-tax basis, of the greatest amount of payments and benefits

provided for hereunder or otherwise, notwithstanding that all or some portion of such Payments may be subject to the Excise Tax. Unless the Company and Executive otherwise agree in writing, any determination required under this Section shall be made by independent tax counsel designated by the Company and reasonably acceptable to Executive ("**Independent Tax Counsel**"), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required under this Section 6(a), Independent Tax Counsel may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code; provided that Independent Tax Counsel shall assume that Executive pays all taxes at the highest marginal rate. The Company and Executive shall furnish to Independent Tax Counsel such information and documents as Independent Tax Counsel may reasonably request in order to make a determination under this Section. The Company shall bear all costs that Independent Tax Counsel may reasonably incur in connection with any calculations contemplated by this Section. In the event that Section 6(a)(ii)(B) above applies, then based on the information provided to Executive and the Company by Independent Tax Counsel, Executive may, in Executive's sole discretion and within thirty (30) days of the date on which Executive is provided with the information prepared by Independent Tax Counsel, determine which and how much of the Payments (including the accelerated vesting of equity compensation awards) to be otherwise received by Executive shall be eliminated or reduced (as long as after such determination the value (as calculated by Independent Tax Counsel in accordance with the provisions of Sections 280G and 4999 of the Code) of the amounts payable or distributable to Executive equals the Reduced Amount). If the Internal Revenue Service (the "**IRS**") determines that any Payment is subject to the Excise Tax, then Section 6(b) hereof shall apply, and the enforcement of Section 6(b) shall be the exclusive remedy to the Company.

(b) **Adjustments**. If, notwithstanding any reduction described in Section 6(a) hereof (or in the absence of any such reduction), the IRS determines that Executive is liable for the Excise Tax as a result of the receipt of one or more Payments, then Executive shall be obligated to surrender or pay back to the Company, within one hundred twenty (120) days after a final IRS determination, an amount of such payments or benefits equal to the "**Repayment Amount**." The Repayment Amount with respect to such Payments shall be the smallest such amount, if any, as shall be required to be surrendered or paid to the Company so that Executive's net proceeds with respect to such Payments (after taking into account the payment of the Excise Tax imposed on such Payments) shall be maximized. Notwithstanding the foregoing, the Repayment Amount with respect to such Payments shall be zero if a Repayment Amount of more than zero would not eliminate the Excise Tax imposed on such Payments or if a Repayment Amount of more than zero would not maximize the net amount received by Executive from the Payments. If the Excise Tax is not eliminated pursuant to this Section 6(b), Executive shall pay the Excise Tax.

7. **MISCELLANEOUS PROVISIONS.**

(ii) **Section 409A**. To the extent (i) any payments to which Executive becomes entitled under this Agreement, or any agreement or plan referenced herein, in connection with Executive's termination of employment with the Company constitute deferred compensation subject to Section 409A of the Code, and (ii) Executive is deemed at the time of such termination of employment to be a "specified" employee under Section 409A of the Code, then such payment or payments shall not be made or commence until the earlier of (x) the expiration of the six (6)-month period measured from the date of Executive's "separation from service" (as such term is at the time defined in regulations under Section 409A of the Code) with the Company; or (y) the date of Executive's death following such separation from service; provided, however, that such deferral shall only be effected to the extent required to avoid adverse tax treatment to Executive, including (without limitation) the additional twenty percent (20%) tax for which Executive would otherwise be liable under Section 409A(a)(1)(B) of the Code in the absence of such deferral. Upon the expiration of the applicable deferral period, any payments which would have otherwise been made

during that period (whether in a single sum or in installments) in the absence of this paragraph shall be paid to Executive or Executive's beneficiary in one lump sum (without interest).

Except as otherwise expressly provided herein, to the extent any expense reimbursement or the provision of any in-kind benefit under this Agreement (or otherwise referenced herein) is determined to be subject to (and not exempt from) Section 409A of the Code, the amount of any such expenses eligible for reimbursement, or the provision of any in-kind benefit, in one calendar year shall not affect the expenses eligible for reimbursement or in kind benefits to be provided in any other calendar year, in no event shall any expenses be reimbursed after the last day of the calendar year following the calendar year in which Executive incurred such expenses, and in no event shall any right to reimbursement or the provision of any in-kind benefit be subject to liquidation or exchange for another benefit.

To the extent that any provision of this Agreement is ambiguous as to its exemption or compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder are exempt from Section 409A to the maximum permissible extent, and for any payments where such construction is not tenable, that those payments comply with Section 409A to the maximum permissible extent. To the extent any payment under this Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. Payments pursuant to this Agreement (or referenced in this Agreement) are intended to constitute separate payments for purposes of Section 1.409A 2(b)(2) of the regulations under Section 409A.

(b) **Other Severance and Acceleration Arrangements**. Except as otherwise specified herein, this Agreement represents the entire agreement between Executive and the Company with respect to any and all severance arrangements, vesting acceleration arrangements, and post-termination stock option exercise period arrangements, and supersedes and replaces any and all prior verbal or written discussions, negotiations, and/or agreements between Executive and the Company relating to the subject matter hereof as may be set forth under, but not limited to, any and all prior agreements governing any Equity Award, any change in control and severance agreements, employment agreement, offer letter, or programs and plans which were previously offered by the Company to Executive, and Executive hereby waives Executive's rights to any and all such other severance arrangements, vesting acceleration arrangements, and post-termination stock option exercise period arrangements, as applicable.

(c) **Dispute Resolution**. To ensure rapid and economical resolution of any and all disputes that might arise in connection with this Agreement, Executive and the Company agree that any and all disputes, claims, and causes of action, in law or equity, arising from or relating to this Agreement or its enforcement, performance, breach, or interpretation, will be resolved solely and exclusively by final, binding, and confidential arbitration, by a single arbitrator, in Los Angeles County, CA, and conducted by JAMs under its then-existing employment rules and procedures. The JAMS rules may be found and reviewed at http://www.jamsadr.com/rules-employment-arbitration. The arbitrator shall issue a written decision that contains the essential findings and conclusions on which the decision is based. The arbitration provisions of this Agreement shall be governed by and enforceable pursuant to the Federal Arbitration Act. In all other respects for provisions not governed by the Federal Arbitration Act, this Agreement shall be construed in accordance with the laws of the State of California, without reference to conflicts of law principles. Nothing in this section, however, is intended to prevent either party from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Each party to an arbitration or litigation hereunder shall be responsible for the payment of its own attorneys' fees.

(d) **Notice**. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid or deposited with an overnight courier, with shipping charges prepaid. In the case of Executive, mailed notices shall be addressed to him or her at the home address which he or she most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(e) **Amendment; Waiver**. This Agreement may not be amended or waived except by a writing signed by Executive and by a duly authorized representative of the Company other than Executive. No provision of this Agreement shall be modified, waived, superseded or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive) and, to the extent it supersedes this Agreement, that this Agreement is referred to by date. No waiver by either party of any breach of, or of compliance with, any

condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(f) **Withholding Taxes**. All payments made under this Agreement shall be subject to reduction to reflect taxes or other charges required to be withheld by law.

(g) **Severability**. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(h) **No Retention Rights**. Nothing in this Agreement shall confer upon Executive any right to continue in service for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Company or any subsidiary of the Company or of Executive, which rights are hereby expressly reserved by each, to terminate his or her service at any time and for any reason, with or without Cause.

(i) **Choice of Law**. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California (other than their choice-of-law provisions).

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties has executed this **Severance & Change in Control Agreement,** as of the day and year this Agreement has been signed by both parties.

EXECUTIVE

By: /s/ Scott L. Burrows
Name: Scott L. Burrows
Title: Chief Financial Officer
Date: April 11, 2021

ARCUTIS BIOTHERAPEUTICS, INC.

By: /s/ Todd Franklin Watanabe
Name: Todd Franklin Watanabe
Title: President and Chief Executive Officer
Date: April 10, 2021

Exhibit 10.3

ARCUTIS BIOTHERAPEUTICS, INC.

$100,000,000 SHARES OF
COMMON STOCK

PAR VALUE $0.0001 PER SHARE

SALES AGREEMENT

May 6, 2021

Cowen and Company, LLC
599 Lexington Avenue
New York, NY 10022

Ladies and Gentlemen:

Arcutis Biotherapeutics, Inc., a Delaware corporation (the "**Company**"), confirms its agreement (this "**Agreement**") with Cowen and Company, LLC ("**Cowen**"), as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell to or through Cowen, acting as agent and/or principal, shares (the "**Placement Shares**") of the Company's common stock, par value $0.0001 per share (the "**Common Stock**"), having an aggregate offering price of up to $100,000,000. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and Cowen shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through Cowen will be effected pursuant to the Registration Statement (as defined below) filed by the Company and which automatically became effective under Rule 462(e) of the Securities Act (as defined below) upon filing with the Securities and Exchange Commission (the "**Commission**"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Common Stock. The Registration Statement is an "automatic shelf registration statement" (as defined in Rule 405) and the Placement Shares (as defined below) have been and remain eligible for registration by the Company on such automatic shelf registration statement.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission an automatic shelf registration statement on Form S-3 (File No. 333-252612), including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**"). The Company has prepared a prospectus supplement specifically relating to the Placement

Shares (the "**Prospectus Supplement**") to the base prospectus included as part of such registration statement. The Company has furnished to Cowen, for use by Cowen, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, and any post-effective amendment thereto, as amended when it became effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act, or any subsequent registration statement on Form S-3 filed pursuant to Rule 415(a)(6) under the Securities Act by the Company with respect to the Placement Shares, is herein called the "**Registration Statement.**" The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement or any additional prospectus supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any "issuer free writing prospectus," as defined in Rule 433 under the Securities Act ("**Rule 433**"), relating to the Placement Shares that (i) is consented to by Cowen, hereinafter referred to as a "**Permitted Free Writing Prospectus,**" (ii) is required to be filed with the Commission by the Company or (iii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g), is herein called the "**Prospectus**." Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering Analysis and Retrieval System ("**EDGAR**").

2. Placements. Each time that the Company wishes to issue and sell the Placement Shares hereunder (each, a "**Placement**"), it will notify Cowen by email notice (or other method mutually agreed to in writing by the parties) (a "**Placement Notice**") containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of shares of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as **Schedule 1**. The Placement Notice shall originate from any of the individuals from the Company set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from Cowen set forth on **Schedule 2**, as such **Schedule 2** may be amended from time to time in accordance herewith. The Placement Notice shall be effective upon receipt by Cowen unless and until (i) in accordance with the notice requirements set forth in Section 4, Cowen declines to accept the

terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares have been sold, (iii) in accordance with the notice requirements set forth in Section 4, the Company suspends or terminates the Placement Notice for any reason in its sole discretion, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of Section 11. The amount of any discount, commission or other compensation to be paid by the Company to Cowen in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in **Schedule 3.** It is expressly acknowledged and agreed that neither the Company nor Cowen will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to Cowen and Cowen does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by Cowen. Subject to the terms and conditions herein set forth, upon the Company's delivery of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, Cowen, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Stock Market, Inc. ("**Nasdaq**") to sell such Placement Shares up to the amount specified in such Placement Notice, and otherwise in accordance with the terms of such Placement Notice. Cowen will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the volume-weighted average price of the Placement Shares sold, and the Net Proceeds (as defined below) payable to the Company. In the event the Company engages Cowen for a sale of Placement Shares that would constitute a "block" within the meaning of Rule 10b-18(a)(5) under the Exchange Act (a "**Block Sale**"), the Company will provide Cowen, at Cowen's request and upon reasonable advance notice to the Company, on or prior to the Settlement Date (as defined below), the opinions of counsel, accountant's letter and officers' certificates set forth in Section 8 hereof, each dated the Settlement Date, and such other documents and information as Cowen shall reasonably request. Cowen may sell Placement Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, including without limitation sales made through Nasdaq or on any other existing trading market for the Common Stock. Cowen may sell Placement Shares in negotiated transactions only if expressly authorized by the Company in a Placement Notice. Cowen shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that Cowen will be successful in selling Placement Shares, and (ii) Cowen will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by Cowen to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such

Placement Shares as required under this Section 3. For the purposes hereof, "**Trading Day**" means any day on which the Company's Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

Notwithstanding any other provision of this Agreement, the Company shall not offer, sell or deliver, or request the offer or sale, of any Placement Shares pursuant to this Agreement and, by notice to Cowen given by telephone (confirmed promptly by email), shall cancel any instructions for the offer or sale of any Placement Shares, and Cowen shall not be obligated to offer or sell any Placement Shares, (i) during any period in which the Company is, or could be deemed to be, in possession of material non-public information, or (ii) at any time from and including the date on which the Company shall issue a press release containing, or shall otherwise publicly announce, its earnings, revenues or other results of operations (an "**Earnings Announcement**") through and including the time that the Company files a Quarterly Report on Form 10-Q or an Annual Report on Form 10-K that includes consolidated financial statements as of and for the same period or periods, as the case may be, covered by such Earnings Announcement.

4. Suspension of Sales.

(a) The Company or Cowen may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on **Schedule 2**), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or impair either party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a suspension is in effect any obligation under Sections 7(m), 7(n), and 7(o) with respect to the delivery of certificates, opinions, or comfort letters to Cowen, shall be waived, provided, however, that the Company shall deliver such certificates, opinions and comfort letters if such suspension is revoked prior to the next occurring Bring-Down Date. Each of the parties agrees that no such notice under this Section 4 shall be effective against the other unless it is made to one of the individuals named on **Schedule 2** hereto, as such schedule may be amended from time to time.

(b) If either Cowen or the Company has reason to believe that the exemptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are not satisfied with respect to the Common Stock, it shall promptly notify the other party, and Cowen may, at its sole discretion, suspend sales of the Placement Shares under this Agreement.

(c) The Registration Statement became effective on February 1, 2021 upon filing with the Commission. Notwithstanding any other provision of this Agreement, during any period in which the Registration Statement is no longer effective under the Securities Act, the Company shall promptly notify Cowen, the Company shall not request the sale of any Placement Shares, and Cowen shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "**Settlement Date**" and the first such settlement date, the "**First Delivery Date**"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "**Net Proceeds**") will be equal to the aggregate sales price received by Cowen at which such Placement Shares were sold, after deduction for (i) Cowen's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to Cowen hereunder pursuant to Section 7(g) (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting Cowen's or its designee's account (provided Cowen shall have given the Company written notice of such designee prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form. On each Settlement Date, Cowen will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. Cowen will be responsible for providing DWAC instructions or instructions for delivery by other means with regard to the transfer of the Placement Shares being sold. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date (other than as a result of a failure by Cowen to provide instructions for delivery), the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 9(a) (Indemnification and Contribution) hereto, it will (i) hold Cowen harmless against any loss, claim, damage, or reasonable and documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to Cowen (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

6. Representations and Warranties of the Company. Except as disclosed in the Registration Statement or the Prospectus, the Company represents and warrants to, and agrees with, Cowen that, unless such representation, warranty or agreement specifies otherwise, as of (i) the date of this Agreement, (ii) each Time of Sale (as defined below), (iii) each Settlement Date, and (iv) each Bring-Down Date (as defined below) (each date included in (i) through (iv), a "**Representation Date**"):

(a) The Registration Statement became effective automatically upon filing with the Commission under the Securities Act. The Registration Statement is an "automatic shelf registration statement" on Form S-3 as defined in Rule 405 of the Securities Act and was filed not earlier than three (3) years prior to the date hereof. No stop order suspending the

effectiveness of the Registration Statement or any post-effective amendment thereto is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, contemplated or threatened by the Commission. The Company meets the requirements for use of Form S3 under the Securities Act. The sale of the Placement Shares hereunder meets the requirements or General Instruction I.B.1 of Form S-3.

(b) The Prospectus when filed complied and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it became effective or its date, as applicable, complied and as of each each Representation Date, complied and will comply in all material respects with the Securities Act and did not and, as of each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date, did not and, as of each Representation Date, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to Agent's Information (as defined below). There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. As used herein, "**Time of Sale**" means with respect to each offering of Placement Shares pursuant to this Agreement, the time of Cowen's initial entry into contracts with purchasers for the sale of such Placement Shares.

(c) The Company has delivered to Cowen one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as Cowen has reasonably requested. The Registration Statement, the Prospectus and any Permitted Free Writing Prospectus (to the extent any such Permitted Free Writing Prospectus was required to be filed with the Commission) delivered to Cowen for use in connection with the public offering of the Placement Shares contemplated herein have been and will be identical to the versions of such documents transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

(d) Subsequent to the respective dates as of which information is given in the Prospectus, the Company has not, (i) sustained any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree or (ii) entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company or incurred any liability or obligation, direct or contingent, that is material to the Company, in each case, other than as set forth or contemplated in the Prospectus; and, since the respective

dates as of which information is given in the Registration Statement and the Prospectus, there has not been (x) any change in the capital stock of the Company (other than as a result of (i) the exercise, if any, of stock options or the award, if any, of stock options, restricted stock or other awards in the ordinary course of business pursuant to the Company's equity plans that are described in the Registration Statement and the Prospectus or (ii) the issuance, if any, of shares of Common Stock upon conversion of Company securities as described in the Registration Statement and the Prospectus), long-term debt of the Company or (y) any Material Adverse Effect (as defined below); as used in this Agreement, "**Material Adverse Effect**" or "**Material Adverse Change**" shall mean any material adverse change or effect, or any development involving a prospective material adverse change or effect, in or affecting (i) the business, properties, general affairs, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries (as defined below), except as set forth or contemplated in the Prospectus, or (ii) the ability of the Company to perform its obligations under this Agreement, including the issuance and sale of the Placement Shares.

(e) The Company and its Subsidiaries do not own any real property and the Company has good and marketable title to all personal property owned by it (other than with respect to Intellectual Property (as defined below), which is addressed exclusively in subsection (ii)) which is material to the business of the Company and its Subsidiaries, free and clear of all liens, encumbrances and defects except such as are described in the Prospectus or such as do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company and its Subsidiaries; and any real property and buildings held under lease by the Company and its Subsidiaries are held by the Company or its Subsidiaries, to its knowledge, under valid, subsisting and enforceable leases with such exceptions as are not material and do not materially interfere with the use made and currently proposed to be made of such property and buildings by the Company and its Subsidiaries.

(f) The Company has been (i) duly organized and is validly existing and in good standing under the laws of its jurisdiction of organization, with power and authority (corporate and other) to own and/or lease its properties and conduct its business as described in the Prospectus, and (ii) duly qualified as a foreign corporation for the transaction of business and is in good standing (where such concept exists) under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, except, in the case of this clause (ii), where the failure to be so qualified or in good standing would not, individually or in the aggregate, have a Material Adverse Effect.

(g) Each subsidiary of the Company (each a "**Subsidiary**") has been duly organized and is validly existing as a corporation or limited liability company in good standing under the laws of the jurisdiction of its organization and has the requisite power and authority to own, lease and operate its properties and to conduct its business as described in the Prospectus. Each of the Company and its Subsidiaries is duly qualified as a foreign corporation or foreign partnership to transact business and is in good standing under the laws of the jurisdiction of its incorporation or formation and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except for such jurisdictions where the failure to so qualify or to be in good standing would not, individually or in the aggregate, result in a Material Adverse Effect. Except as described in the Prospectus, all of the

issued and outstanding equity interests of the Subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company free and clear of any security interest, mortgage, pledge, lien, encumbrance or claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Company's Annual Report on Form 10-K for the most recently ended fiscal year and other than (i) those subsidiaries not required to be listed on Exhibit 21.1 by Item 601 of Regulation S-K under the Exchange Act and (ii) those subsidiaries formed since the last day of the most recently ended fiscal year.

(h) The Company has an authorized capitalization as set forth in the Registration Statement and the Prospectus and all of the issued shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and conform in all material respects to the description of the capital stock contained in the Registration Statement and Prospectus.

(i) The Placement Shares, when issued and delivered, will be duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be duly authorized, validly issued, fully paid and nonassessable and will conform in all material respects to the description of the Common Stock contained in the Registration Statement and the Prospectus; and the issuance of the Placement Shares is not subject to any preemptive or similar rights except as have been validly waived or complied with.

(j) The issue and sale of the Placement Shares and the compliance by the Company with this Agreement and the consummation of the transactions contemplated in this Agreement and the Prospectus will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, (A) any indenture, mortgage, deed of trust, loan agreement, license, lease or other agreement or instrument to which the Company or any Subsidiary is a party or by which the Company or any Subsidiary is bound or to which any of the property or assets of the Company or any Subsidiary is subject, (B) the certificate of incorporation or by-laws (or other applicable organizational document) of the Company or any Subsidiary, or (C) any statute or any judgment, order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any Subsidiary or any of its properties, except, in the case of clauses (A) and (C), for such defaults, breaches, or violations that would not, individually or in the aggregate, have a Material Adverse Effect; and no consent, approval, authorization, order, registration or qualification of or with any such court or governmental agency or body is required for the issue and sale of the Placement Shares or the consummation by the Company of the transactions contemplated by this Agreement, except such as have been obtained under the Act**,** the approval by the Financial Industry Regulatory Authority ("**FINRA**") of the underwriting terms and arrangements and such consents, approvals, authorizations, registrations or qualifications as may be required under state securities or Blue Sky laws in connection with the sale of the Placement Shares.

(k) Neither the Company nor any Subsidiary is (i) in violation of its certificate of incorporation or by-laws (or other applicable organizational document), (ii) in violation of any statute or any judgment, order, rule or regulation of any court or governmental agency or body

having jurisdiction over the Company or any Subsidiary or any of its properties or assets, or (iii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the performance or observance of any obligation, agreement, term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, license, lease or other agreement or instrument to which it is a party or by which it or any of its properties or assets may be bound, except, in the case of the foregoing clauses (ii) and (iii), for such violations or defaults as would not, individually or in the aggregate, have a Material Adverse Effect.

(l) The statements set forth in the Registration Statement and the Prospectus under the caption "Description of Capital Stock", insofar as they purport to constitute a summary of the terms of the Stock, are accurate, complete and fair in all material respects.

(m) Other than as set forth in the Prospectus, there are no legal or governmental proceedings pending to which the Company or any Subsidiary, to the Company's knowledge, any officer or director of the Company or any Subsidiary, is a party or of which any property or assets of the Company or any Subsidiary is the subject which, if determined adversely to the Company (or such officer or director), would individually or in the aggregate have a Material Adverse Effect; and, to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or others.

(n) The Company is not and, after receipt of payment for the Placement Shares and the application of the proceeds as described in the Prospectus, will not be, required to register as an "investment company", as such term is defined in the Investment Company Act of 1940, as amended (the "**Investment Company Act**").

(o) (A) (i) At the time of filing the Registration Statement, (ii) at the time of the most recent amendment thereto for the purposes of complying with Section 10(a)(3) of the Act (whether such amendment was by post-effective amendment, incorporated report filed pursuant to Section 13 or 15(d) of the Exchange Act or form of prospectus), and (iii) at the time the Company or any person acting on its behalf (within the meaning, for this clause only, of Rule 163(c) under the Act) made any offer relating to the Placement Shares in reliance on the exemption of Rule 163 under the Act, the Company was a "well-known seasoned issuer" as defined in Rule 405 under the Act; and (B) at the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or any offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) under the Act) of the Placement Shares, and at the date hereof, the Company was not and is not an "ineligible issuer," as defined under Rule 405 under the Act.

(p) Ernst & Young LLP, who has certified certain financial statements of the Company, is an independent public accounting firm as required by the Act and the rules and regulations of the Commission thereunder.

(q) There are no off-balance sheet arrangements (as defined in Regulation S-K Item 303(a)(4)(ii) of the Act) that have or are reasonably likely to have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures or capital resources.

(r) The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act that (i) complies with the requirements of the Exchange Act applicable to the Company, (ii) has been designed by the Company's principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and (iii) is designed to provide reasonable assurance that (A) transactions are executed in accordance with management's general or specific authorization, (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets, (C) access to assets is permitted only in accordance with management's general or specific authorization and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences ; and the Company's internal control over financial reporting is effective and the Company is not aware of any material weaknesses in its internal control over financial reporting (it being understood that this subsection shall not require the Company to comply with Section 404 of the Sarbanes Oxley Act of 2002 as of an earlier date than it would otherwise be required to so comply under applicable law).

(s) Since the date of the latest audited financial statements included or incorporated by reference in the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting.

(t) The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act) that comply with the requirements of the Exchange Act applicable to the Company; such disclosure controls and procedures have been designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and principal financial officer by others within the Company; and such disclosure controls and procedures are effective in all material respects.

(u) The Company has all requisite corporate power and authority to execute and deliver, and to perform its obligations under, this Agreement. This Agreement has been duly authorized, executed and delivered by the Company and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(v) Neither the Company nor any of its Subsidiaries nor any of their respective directors, officers, or employees or, to the knowledge of the Company, any agent, representative, affiliate or other person associated with or acting on behalf of the Company or any Subsidiary has (i) made, offered, promised, authorized, or approved any unlawful contribution, gift, entertainment or other unlawful expense (or taken or will take any action in furtherance thereof); (ii) made, offered, promised, authorized, or approved the provision or receipt of money, property, gifts, or anything else of value, directly or indirectly, to or from any person, including any

government official (including any officer, employee, or director of a government, government-owned or controlled entity, or public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office), in order to influence official action, improperly obtain or retain business, or otherwise in violation of applicable anti-corruption laws (or taken or will take any action in furtherance thereof); (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) will use, directly or indirectly, the proceeds of the offering in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money or anything else of value, to any person in violation of any applicable anti-corruption laws. The Company and each Subsidiary has instituted, maintains and enforces, and will continue to maintain and enforce, policies and procedures designed to promote and achieve compliance with all applicable anti-bribery and anti-corruption laws and with the representations and warranties contained herein.

(w) The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with the requirements of applicable financial recordkeeping and reporting requirements and anti-money laundering laws in jurisdictions where the Company and its Subsidiaries conduct business, including, but not limited to, the Bank Secrecy Act of 1970, as amended by the USA PATRIOT ACT of 2001, and the rules, regulations, and guidelines issued or promulgated thereunder, (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company and its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(x) The Company and each Subsidiary is and at all times has been in compliance in all material respects with all applicable foreign, federal, state and local healthcare laws, rules and regulations, including, without limitation, (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.); (ii) all healthcare related fraud and abuse laws, including, without limitation, the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), the civil monetary penalties law (42 U.S.C. § 1320a-7a), the exclusion law (42 U.S.C. § 1320a-7), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), all criminal laws relating to healthcare fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1035, 1347 and 1349, the healthcare fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") (42 U.S.C. §§1320d et seq.), the Medicare statute (Title XVIII of the Social Security Act), and the Medicaid statute (Title XIX of the Social Security Act); and (iii) the patient privacy, data security and breach notification provisions under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. §§17921 et seq.); each as amended and the regulations promulgated pursuant to such laws (collectively, "**Healthcare Laws**"). The Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any arbitrator, court, governmental body, regulatory body, administrative agency, or other authority, body, or agency having jurisdiction over the Company or any Subsidiary (each, a "**Governmental Entity**") or third party alleging that any product operation or activity is in violation of any Healthcare Laws, and, to the Company's Knowledge, no such

claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened, except in each case as would not, individually or in the aggregate, have a Material Adverse Effect. Neither the Company nor any Subsidiary is party to and does not have any ongoing reporting obligations pursuant to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement with or imposed by any governmental or regulatory authority. Additionally, neither the Company, nor its Subsidiaries, nor any of their respective employees, officers or directors, or to the Company's knowledge, agents, is or has been excluded, suspended, debarred or is otherwise ineligible from participation in any U.S. state or federal healthcare program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

(y) The Company and each Subsidiary possesses such material permits, licenses, approvals, consents, exemptions, registrations, and other authorizations (collectively, "**Governmental Licenses**") issued by the appropriate Governmental Entities necessary to conduct the business now operated by them. The Company is in material compliance with the terms and conditions of all Governmental Licenses, and all Governmental Licenses are valid and in full force and effect. Neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or material modification of any Governmental Licenses.

(z) The Company and its Subsidiaries: (i) have not received any Form 483, notice of adverse finding, warning letter, untitled letter or other written correspondence, or to the Company's knowledge any oral or other notice from any governmental authority alleging or asserting material noncompliance with any Healthcare Laws or the terms of any Governmental Licenses; (ii) have not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Healthcare Laws or Governmental Licenses and have no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, except in each case as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) (a) have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Healthcare Laws or Governmental Licenses, (b) all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct and not misleading in all material respects on the date filed (or were corrected or supplemented by a subsequent submission), and (c) the Company is not aware of any reasonable basis for any material liability with respect to such filings; and (iv) has not, and to the knowledge of the Company, the Company's officers, employees and agents have not, made any untrue statement of a material fact or fraudulent statement to any Governmental Entity or failed to disclose a material fact required to be disclosed to any Governmental Entity.

(aa) The preclinical tests and clinical trials that are described in the Registration Statement or Prospectus were and, if still pending, are being conducted in all material respects in accordance with all applicable Healthcare Laws, including the Federal Food, Drug, and Cosmetic

Act and the regulations set forth at 21 C.F.R. Parts 50, 54, 56, 58 and 312; the Company has no knowledge of any studies or tests the results of which are inconsistent with, or otherwise call into question, the results described in the Prospectus; and neither the Company nor any Subsidiary has received any written notices or other correspondence from any Governmental Entity requiring the termination, suspension or material modification of any preclinical tests or clinical trials.

(ab) Neither the Company nor any of its Subsidiaries nor any of their respective directors, officers, or employees or, to the knowledge of the Company, any agent, representative, or affiliate of the Company or any of its Subsidiaries is, or is owned or controlled by one or more persons that are: (i) the subject or the target of any sanctions administered or enforced by the U.S. Government, including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person," the European Union, Her Majesty's Treasury, the United Nations Security Council, or other relevant sanctions authority (collectively, "**Sanction**s"), or (ii) located, organized or resident in a country or territory that is the subject or target of Sanctions (including, without limitation, Crimea, Cuba, Iran, North Korea, and Syria). The Company will not directly or indirectly use the proceeds of the offering of the Placement Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (x) to fund or facilitate any activities of or business with any person, or in any country or territory, that, at the time of such funding or facilitation, is the subject or the target of Sanctions or (y) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

(ac) The financial statements included or incorporated by reference in the Registration Statement and the Prospectus, together with the related schedules and notes, present fairly, in all material respects, the financial position of the Company and its Subsidiaries at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("**GAAP**") applied on a consistent basis throughout the periods involved. The supporting schedules, if any, present fairly in accordance with GAAP the information required to be stated therein. The selected financial data and the summary financial information included in the Registration Statement and the Prospectus present fairly in all material respects the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement or the Prospectus under the Act or the rules and regulations promulgated thereunder.

(ad) There are no debt securities, convertible securities or preferred stock issued or guaranteed by the Company that are rated by a "nationally recognized statistical rating organization", as such term is defined in Section 3(a)(62) under the Exchange Act.

(ae) From the time of initial confidential submission of the registration statement relating to the Company's initial public offering with the Commission through the date hereof,

the Company has been and is an "emerging growth company" as defined in Section 2(a)(19) of the Act (an "**Emerging Growth Company**").

(af) There are no persons with registration rights or other similar rights to have any securities registered pursuant to the Registration Statement or otherwise registered by the Company under the Act except as have been validly waived or complied with.

(ag) The Company's and each of the Subsidiary's information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its Subsidiaries as currently conducted, and, to the knowledge of the Company, are free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and each of the Subsidiaries have implemented and maintained commercially reasonable controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data (including all personal, personally identifiable, sensitive, confidential or regulated data ("**Personal Data**")) used in connection with its businesses, and there have been no breaches, violations, outages or unauthorized uses of or accesses to the same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and each Subsidiary is presently, and at all times has been, in material compliance with all applicable data privacy and security laws and regulations, including the European Union General Data Protection Regulation) (EU 2016/679), and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data, and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, have a Material Adverse Effect. The Company and each Subsidiary has taken or is currently taking all necessary actions to comply with all other applicable laws and regulations with respect to Personal Data that have been announced as of the date hereof as becoming effective within 12 months after the date hereof, and for which any non-compliance with the same would be reasonably likely to create a material liability, as soon as reasonably practicable as they take effect.

(ah) The Company and the Subsidiaries have filed all tax returns required to be filed by it through the date hereof, or has duly requested extensions thereof (except where the failure to file would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect), and has paid all taxes shown as due thereon (except for cases in which the failure to file or pay would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect or, except as currently being contested in good faith and for which reserves required by U.S. GAAP have been created in the financial statements of the Company), and all such tax returns are true and correct in all material respects. No deficiencies for taxes of the Company or any Subsidiary has been assessed by a tax authority, and no deficiencies for taxes of the Company or any Subsidiary has, to the Company's knowledge, been proposed by a

tax authority, except for such deficiencies as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(ai) The Company and its Subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, know-how, trade secrets and other intellectual property described in the Registration Statement and the Prospectus as being owned or licensed by the Company or the Subsidiaries or which are necessary for the conduct of the Company's or any Subsidiary's business as currently conducted or as currently proposed to be conducted in the Registration Statement and the Prospectus (collectively, "**Intellectual Property**"), and there are no unreleased liens or security interests which have been filed against any of the patents owned by the Company or any Subsidiary. To the Company's knowledge: (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement and the Prospectus as licensed to the Company or the Subsidiaries, and the Company and the Subsidiaries have taken all reasonable steps necessary to secure their respective interests in the Intellectual Property from its employees and contractors; (ii) there is no infringement, misappropriation or violation by third parties of any Intellectual Property; (iii) neither the Company nor any of the Subsidiaries is infringing, misappropriating or violating the intellectual property rights of third parties; (iv) the Company and the Subsidiaries are the sole owner of the Intellectual Property owned by them and has the valid right to use such Intellectual Property; and (v) no employee of the Company or any Subsidiary is in or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or any Subsidiary. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's or any Subsidiary's rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that either the Company or any Subsidiary infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement and the Prospectus as under development, infringe, misappropriate or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. The Company and each Subsidiary has complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or any Subsidiary, and all such agreements are in full force and effect. The product candidates described in the Registration Statement and the Prospectus as under development by the Company or any Subsidiary fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company or any Subsidiary.

(aj) All patents and patent applications owned by or exclusively licensed to the Company or any Subsidiary or under which the Company or any Subsidiary has rights have, to

the knowledge of the Company, been duly and properly filed and each issued patent is being diligently maintained; to the knowledge of the Company, the parties prosecuting such applications have complied with their duty of candor and disclosure to the U.S. Patent and Trademark Office (the "**USPTO**") in connection with such applications; to the Company's knowledge, there is no prior art material to any patent or patent application of the Intellectual Property of the Company that may render any U.S. patent held by the Company or any Subsidiary invalid or any U.S. patent application held by the Company or any Subsidiary unpatentable; and the Company is not aware of any facts required to be disclosed to the USPTO that were not disclosed to the USPTO and which would preclude the grant of a patent in connection with any such application or would reasonably be expected to form the basis of a finding of invalidity with respect to any patents that have been issued with respect to such applications.

(ak) (i) the Company and each Subsidiary (x) is in compliance with all, and has not violated any, applicable federal, state, local and foreign laws, rules, regulations, requirements, decisions, judgments, decrees, orders and other legally enforceable requirements relating to pollution or the protection of human health or safety, the environment, natural resources, hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "**Environmental Laws**"); (y) has received and is in compliance with all, and have not violated any, permits, licenses, certificates or other authorizations or approvals required of it under any Environmental Laws to conduct its businesses; and (z) has not received written notice of any actual or potential liability by the Company or any Subsidiary or obligation of the Company or any Subsidiary under or relating to, or any actual or potential violation of, any Environmental Laws by the Company or any Subsidiary, including for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, and have no knowledge of any event or condition that would reasonably be expected to result in any such notice, and (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company or any Subsidiary, except in the case of each of (i) and (ii) above, for any such matter as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in each of the Registration Statement and the Prospectus, (x) there is no proceeding that is pending, or that is known by the Company to be contemplated, against the Company or any Subsidiary under any Environmental Laws in which a governmental entity is also a party, other than such proceeding regarding which the Company reasonably believes no monetary sanctions of $100,000 or more will be imposed, (y) the Company is not aware of any facts or issues regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that would, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and (z) the Company does not anticipate material capital expenditures relating to any Environmental Laws.

(al) No labor disturbance by or dispute with the employees of the Company or any Subsidiary exists or, to the knowledge of the Company, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its principal suppliers, manufacturers, customers or contractors, which, in either case, would, individually or in the aggregate, result in a Material Adverse Effect.

(am))(i) Except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"), for which the Company or any member of its "Controlled Group" (defined as any entity, whether or not incorporated, that is under common control with the Company within the meaning of Section 4001(a)(14) of ERISA or any entity that would be regarded as a single employer with the Company under Section 414(b),(c),(m) or (o) of the Internal Revenue Code of 1986, as amended (the "Code")) would have any liability (each, a "**Plan**") has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan, excluding transactions effected pursuant to a statutory or administrative exemption; (ii) none of the Plans are subject to Section 412 of the Code or Section 302 or Title IV of ERISA; (iv) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any material liability under Title IV of ERISA in respect of a Plan (including a "multiemployer plan" within the meaning of Section 4001(a)(3) of ERISA); and (v) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

(an) There are no business relationships or related-party transactions involving the Company or any Subsidiary or any other person required to be described in the Prospectus that have not been described as required.

(ao) The Company and each Subsidiary has insurance against such losses and risks and in such amounts as are, in the Company's reasonable judgment, prudent and customary for the size of the business and the industry in which it is engaged and neither the Company nor any Subsidiary has not received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance nor does the Company have any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.

(ap) Except for Cowen, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(aq) The Company has not, and, to its knowledge, no one acting on its behalf (other than Cowen) has taken, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Placement Shares.

(ar) The statistical and market-related data included in the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects.

(as) The interactive data in XBRL, if any, included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto to the extent required.

(at) The Company has not distributed and will not distribute, prior to the completion of Cowen's distribution of the Placement Shares, any offering material in connection with the offering and sale of the Placement Shares other than the Prospectus or the Registration Statement.

(au) The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the Settlement Dates, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(av) The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or Section 12(g) of the Exchange Act and is listed on the Nasdaq, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing. All of the Placement Shares that have been or may be sold under this Agreement have been approved for listing on the Nasdaq, subject to official notice of issuance; the Company has taken all necessary actions to ensure that, upon and at all times after the Nasdaq shall have approved the Placement Shares for listing, it will be in compliance with all applicable corporate governance requirements set forth in the Nasdaq's listing rules that are then in effect.

(aw) Except as described in the Prospectus, there are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of the members of any of them.

(ax) The Company has not relied upon Cowen or legal counsel for Cowen for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(ay) The Company has not been advised, and has no reason to believe, that it and each of its subsidiaries are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not result in a Material Adverse Change.

Any certificate signed by an officer of the Company and delivered to Cowen or to counsel for Cowen pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company to Cowen as to the matters set forth therein.

The Company acknowledges that Cowen and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to Cowen, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with Cowen that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by Cowen under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify Cowen promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information (insofar as it relates to the transactions contemplated hereby), (ii) the Company will prepare and file with the Commission, promptly upon Cowen's reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in Cowen's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by Cowen (*provided*, *however*, that the failure of Cowen to make such request shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement and *provided*, *further*, that the only remedy Cowen shall have with respect to the failure by the Company to make such filing (other than Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to Cowen within a reasonable period of time before the filing and Cowen has not reasonably objected thereto in writing within two business days (*provided*, *however*, that (A) the failure of Cowen to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement, (B) the Company has no obligation to provide Cowen any advance copy of such filing or to provide Cowen an opportunity to object to such filing if the filing does not name Cowen and does not relate to the transaction herein and (C) the only remedy Cowen shall have with respect to the failure by the Company to provide Cowen with such copy, to make such filings, or to obtain such consent (other than Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement)) and the Company will furnish to Cowen at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act, and (v) prior to the termination of this Agreement, the Company will notify Cowen if at any time the Registration Statement shall no longer be effective as a result of the passage of time pursuant to Rule 415 under the Securities Act or otherwise.

(b) Notice of Commission Stop Orders. The Company will advise Cowen, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates taking into account any extensions available under the Exchange Act**)** all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify Cowen to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; provided, however, that the Company may delay any such amendment or supplement if, in the reasonable judgment of the Company, it is in the best interest of the Company to do so, provided that no Placement Notice is in effect during such time.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as Cowen reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however,* that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to Cowen and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during

such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as Cowen may from time to time reasonably request and, at Cowen's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided*, *however,* that the Company shall not be required to furnish any document (other than the Prospectus) to Cowen to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of Section 11 hereunder, will pay the following expenses all incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for Cowen in connection therewith shall be paid by Cowen except as set forth in (vii) below), (iv) the printing and delivery to Cowen of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, of the Commission, (vii) the filing fees and associated legal expenses of Cowen's outside counsel for filings with the FINRA Corporate Financing Department, such legal expense reimbursement not to exceed $15,000 and, (viii) the reasonable fees and disbursements of Cowen's counsel in an amount not to exceed $50,000.

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for 5 trading days following the termination of any Placement Notice given hereunder, the Company shall provide Cowen notice as promptly as reasonably practicable before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with the (i) offer, issuance, grant or sale of Common Stock (including restricted Common Stock), options to purchase shares of Common Stock or Common Stock, restricted stock units or other equity awards issuable upon the exercise of options or other equity awards pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Prospectus, (ii) the offer or issuance of securities in connection with an acquisition, merger or sale or purchase or license of assets, (iii) the issuance or sale of Common Stock pursuant to any

dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to Cowen in advance or (iv) any shares of Common Stock, or securities convertible into or exercisable for Common Stock, offered and sold in a privately negotiated transaction to vendors, customers, investors, strategic partners or potential strategic partners and otherwise conducted in a manner so as not to be integrated with the offering of Placement Shares hereby or (v) the issuance or sale of any shares of common stock issuable upon the exchange, conversion or redemption of securities or the exercise of warrants, options or other rights in effect or outstanding or disclosed in filings by the Company available on EDGAR or otherwise in writing to Cowen prior to the date of the applicable Placement Notice. Notwithstanding the foregoing provisions, subject to the Company's compliance with the notice provisions set forth in this Section 7(i), nothing herein shall be construed to restrict the Company from entering into and/or consummating a committed underwritten equity offering or other similar offering of its registered securities, or otherwise prohibit the issuance of its equity securities in a private placement transaction, or obtain prior written consent, to do any of the foregoing.

(j) Change of Circumstances. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise Cowen promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to Cowen pursuant to this Agreement.

(k) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by Cowen or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as Cowen may reasonably request.

(l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing under Rule 424(b), a "**Filing Date**"), and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market. The Company shall disclose in its quarterly reports on Form 10-Q and in its annual report on Form 10-K, the number of the Placement Shares sold through Cowen under this Agreement, and the gross proceeds and Net Proceeds to the Company from the sale of the Placement Shares and the compensation paid by the Company with respect to sales of the Placement Shares pursuant to this Agreement during the relevant quarter or, in the case of an Annual Report on Form 10-K, during the fiscal year covered by such Annual Report and the fourth quarter of such fiscal year.

(m) Bring-Down Dates; Certificate. On or prior to the First Delivery Date and each time (i) the Company files the Prospectus relating to the Placement Shares or amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(l) of this Agreement) by means

of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) the Company files an annual report on Form 10-K under the Exchange Act; (iii) the Company files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) the Company files a report on Form 8-K containing amended financial information (other than an earnings release) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a **"Bring-Down Date"**); the Company shall furnish Cowen with a certificate, in the form attached hereto as Exhibit 7(m) within three (3) Trading Days of any Bring-Down Date if requested by Cowen. The requirement to provide a certificate under this Section 7(m) shall be waived for any Bring-Down Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Bring-Down Date) and the next occurring Bring-Down Date; provided, however, that such waiver shall not apply for any Bring-Down Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Bring-Down Date when the Company relied on such waiver and did not provide Cowen with a certificate under this Section 7(m), then before the Company delivers the Placement Notice or Cowen sells any Placement Shares, the Company shall provide Cowen with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

(n) Legal Opinion. On or prior to the First Delivery Date and within three (3) Trading Days of each Bring-Down Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause to be furnished to Cowen a written opinion of Latham & Watkins LLP ("Company Counsel"), or other counsel satisfactory to Cowen, in form and substance satisfactory to Cowen and its counsel, dated the date that the opinion is required to be delivered, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided*, *however*, the Company shall be required to furnish to Cowen no more than one counsel for the Company written opinion hereunder per each filing of an annual report on Form 10-K or quarterly report on Form 10-Q; *provided, however* that in lieu of such opinions for subsequent Bring-Down Dates, counsel may furnish Cowen with a letter (a "**Reliance Letter**") to the effect that Cowen may rely on a prior opinion delivered under this Section 7(n) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Bring-Down Date).

(o) Comfort Letter. On or prior to the First Delivery Date and within three (3) Trading Days of each Bring-Down Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause its independent accountants to furnish Cowen letters (the **"Comfort Letters"**), dated the date the Comfort Letter is delivered, in form and substance satisfactory to Cowen, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to Cowen in connection with registered

public offerings (the first such letter, the **"Initial Comfort Letter"**) and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) [Reserved]

(q) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) sell, bid for, or purchase the Common Stock to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than Cowen; provided, however, that the Company may bid for and purchase shares of its common stock in accordance with Rule 10b-18 under the Exchange Act.

(r) Insurance. The Company and its subsidiaries shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.

(s) Compliance with Laws. The Company and each of its subsidiaries shall maintain, or cause to be maintained, all material environmental permits, licenses and other authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and each of its subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial compliance with such permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or be in compliance with such permits, licenses and authorizations could not reasonably be expected to result in a Material Adverse Change.

(t) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act, assuming no change in the Commission's current interpretation as to entities that are not considered an investment company.

(u) Securities Act and Exchange Act. The Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.

(v) No Offer to Sell. Other than a Permitted Free Writing Prospectus, neither Cowen nor the Company (including its agents and representatives, other than Cowen in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Common Stock hereunder.

(w) Sarbanes-Oxley Act. The Company and its subsidiaries will use their best efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.

(x) Affirmation. Each Placement Notice delivered by the Company to Cowen shall be deemed to be (i) an affirmation that the representations, warranties and agreements of the Company herein contained and contained in any certificate delivered to Cowen pursuant hereto are true and correct at the time of delivery of such Placement Notice, and (ii) an undertaking that such representations, warranties and agreements will be true and correct on any applicable Time of Sale and Settlement Date, as though made at and as of each such time (it being understood that such representations, warranties and agreements shall relate to the Registration Statement and the Prospectus as amended and supplemented to the time of such Placement Notice acceptance).

(y) Renewal. If immediately prior to the third anniversary (the "**Renewal Deadline**") of the initial effective date of the Registration Statement, the aggregate gross sales price of Placement Shares sold by the Company is less than the Maximum Amount and this Agreement has not expired or been terminated, the Company will, prior to the Renewal Deadline, file, if it has not already done so and is eligible to do so, a new shelf registration statement relating to the Placement Shares, in a form satisfactory to Cowen, and, if not automatically effective, will use its best efforts to cause such registration statement to be declared effective within 60 days after the Renewal Deadline. The Company will take all other action necessary or appropriate to permit the issuance and sale of the Placement Shares to continue as contemplated in the expired registration statement relating to the Placement Shares. References herein to the Registration Statement shall include such new shelf registration statement.

8. Conditions to Cowen's Obligations. The obligations of Cowen hereunder with respect to a Placement Notice will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder and thereunder, to the completion by Cowen of a due diligence review satisfactory to Cowen in its reasonable judgment, and to the continuing satisfaction (or waiver by Cowen in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall be effective and shall be available for (i) all sales of Placement Shares issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Shares contemplated to be issued pursuant to any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares

for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. Cowen shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in Cowen's reasonable opinion is material, or omits to state a fact that in Cowen's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Change or any development that could reasonably be expected to result in a Material Adverse Change, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of Cowen (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Company Counsel Legal Opinion. Cowen shall have received the opinions of Company Counsel required to be delivered pursuant to Section 7(n) on or before the date on which such delivery of such opinion is required pursuant to Section 7(n).

(f) Cowen Counsel Legal Opinion. Cowen shall have received from Cooley LLP, counsel for Cowen, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to Section 7(n), with respect to such matters as Cowen may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(g) Comfort Letter. Cowen shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(h) Representation Certificate. Cowen shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

(i) Secretary's Certificate. On or prior to the First Delivery Date, Cowen shall have received a certificate, signed on behalf of the Company by its corporate secretary, in form and substance satisfactory to Cowen and its counsel.

(j) [Reserved]

(k) No Suspension. Trading in the Common Stock shall not have been suspended on Nasdaq.

(l) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to Cowen such appropriate further information, certificates and documents as Cowen may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish Cowen with such conformed copies of such opinions, certificates, letters and other documents as Cowen shall have reasonably requested.

(m) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(n) Approval for Listing. To the extent required by the rules of Nasdaq, the Placement Shares shall either have been (i) approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the issuance of any Placement Notice.

(o) No Termination Event. There shall not have occurred any event that would permit Cowen to terminate this Agreement pursuant to Section 11(a).

9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless Cowen, the directors, officers, partners, employees and agents of Cowen and each person, if any, who (i) controls Cowen within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with Cowen from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable investigative, legal and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which Cowen, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission, (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading or (z) any breach by any of the indemnifying parties of any of their respective representations, warranties and agreements contained in this Agreement; *provided, however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission made in reliance upon and in conformity with solely Agent's Information. "Agent's Information" means, solely, the following information in the Prospectus: the [tenth] paragraph under the caption "Plan of Distribution" in the Prospectus. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) Cowen Indemnification. Cowen agrees to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will

not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or Cowen, the Company and Cowen will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company

from persons other than Cowen, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and Cowen may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and Cowen on the other. The relative benefits received by the Company on the one hand and Cowen on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by Cowen from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and Cowen, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Cowen, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and Cowen agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), Cowen shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of Cowen, will have the same rights to contribution as that party, and each officer and director of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of Cowen, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. Termination.

(a) Cowen shall have the right by giving written notice as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Change, or any development that could reasonably be expected to result in a Material Adverse Change has occurred that, in the reasonable judgment of Cowen, may materially impair the ability of Cowen to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder, or (iii) any other condition of Cowen's obligations hereunder is not fulfilled, or (iv), any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If Cowen elects to terminate this Agreement as provided in this Section 11(a), Cowen shall provide the required written notice as specified in Section 12 (Notices).

The Company shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(b) Cowen shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(c) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through Cowen on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(d) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided*,

however, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 16 and Section 17 shall remain in full force and effect.

Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided*, *however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by Cowen or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement. Upon termination of this Agreement, the Company shall not have liability to Cowen for any discount, commission or other compensation with respect to any Placement Shares not otherwise sold by Cowen under this Agreement, except with respect to reimbursement of expenses pursuant to Section 7(g)

Subject to the additional limitations set forth in Section 7 of this Agreement, in the event of termination of this Agreement prior to the sale of any Placement Shares. Cowen shall be entitled only to reimbursement of its out of pocket expenses actually incurred.

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to Cowen, shall be delivered to Cowen at Cowen and Company, LLC, 599 Lexington Avenue, New York, NY 10022, fax no. 646-562-1130, Attention: General Counsel, email: Bradley.friedman@cowen.com, with a copy to Cooley LLP, fax no. 212-479-6275, attention: Daniel I. Goldberg; or if sent to the Company, shall be delivered to Arcutis Biotherapeutics, Inc., 2945 Townsgate Road, Suite 110, Westlake Village, CA 91361, attention: General Counsel , email: kklein@arcutis.com, with a copy to Latham & Watkins LLP, attention: Brian Cuneo, email: brian.cuneo@lw.com. Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and Cowen and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided*, *however*, that Cowen may assign its rights and obligations hereunder to an affiliate of Cowen without obtaining the Company's consent.

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.

15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and Cowen. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

17. Waiver of Jury Trial. The Company and Cowen each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

18. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) Cowen has been retained solely to act as an arm's length contractual counterparty to the Company in connection with the sale of the Placement Shares contemplated hereby and that no fiduciary, advisory or agency relationship between the Company and Cowen has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether Cowen has advised or is advising the Company on other matters;

(b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Company has been advised that Cowen and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that Cowen has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) the Company waives, to the fullest extent permitted by law, any claims it may have against Cowen, for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that Cowen shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.

19. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or by electronic delivery of a portable document format (PDF) file (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com).

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding between the Company and Cowen, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and Cowen.

Very truly yours,

COWEN AND COMPANY, LLC

By: /s/ Michael Murphy
Title: Managing Director

ACCEPTED as of the date first-above written:

ARCUTIS BIOTHERAPEUTICS, INC.

By: /s/ Scott L. Burrows
Title: Chief Financial Officer

SCHEDULE 1

FORM OF PLACEMENT NOTICE

From: [ ]
Cc: [ ]
To: [ ]
Subject: Cowen At the Market Offering—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Arcutis Biotherapeutics, Inc. (the "Company"), and Cowen and Company, LLC ("Cowen") dated May 6, 2021 (the "Agreement"), I hereby request on behalf of the Company that Cowen sell up to [ ] shares of the Company's common stock, par value $0.0001 per share, at a minimum market price of $_____ per share. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold].

SCHEDULE 2

Notice Parties

Company

Todd Franklin Watanabe	President and Chief Executive Officer
Scott L. Burrows	Chief Financial Officer

Cowen

Michael J. Murphy Managing Director

William Follis Managing Director

SCHEDULE 3

Compensation

Cowen shall be paid compensation equal to 3.0% of the gross proceeds from the sales of Common Stock pursuant to the terms of this Agreement.

Exhibit 7(m)

OFFICER CERTIFICATE

The undersigned, the duly qualified and elected _____, of Arcutis Biotherapeutics, Inc. ("**Company**"), a Delaware corporation, does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated May 6, 2021 (the "**Sales Agreement**") between the Company and Cowen and Company, LLC, that to the best of the knowledge of the undersigned.

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Change, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

By:_____
Name:
Title:

Date:_____

Exhibit 31.1

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

I, Todd Franklin Watanabe, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 6, 2021

By: /s/ Todd Franklin Watanabe

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

Exhibit 31.2

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

I, Scott L. Burrows, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 6, 2021

By: /s/ Scott L. Burrows

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

Exhibit 32.1

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

In connection with the Quarterly Report of Arcutis Biotherapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and Scott L. Burrows, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 6, 2021 By: /s/ Todd Franklin Watanabe

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

Date: May 6, 2021 By: /s/ Scott L. Burrows

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