ARCUTIS
BIOTHERAPEUTICS

2021 Annual Report

Dear Arcutis Stockholders

Arcutis Biotherapeutics, Inc. was founded in 2016, borne out of our recognition that medical dermatology was in urgent need of therapeutic innovations. Our goal was both simple and bold: to become the leading innovation-driven dermatology company, and to change the course of treatment for people struggling with serious diseases of the skin. Looking back now, I am incredibly proud of the significant strides that our team has made toward meeting this goal, especially in this very productive past year.

During 2021, we continued our track record of successfully advancing our product pipeline. Most significantly, our filing of a New Drug Application with the U.S. Food and Drug Administration for topical roflumilast cream in plaque psoriasis was accepted and is under review, supported by positive data from our pivotal Phase 3 DERMIS program. In addition, we initiated enrollment in three additional Phase 3 programs for other indications using topical roflumilast cream and foam in atopic dermatitis, scalp psoriasis, and seborrheic dermatitis, with topline data from all three programs anticipated by the end of this year. We also expanded our patent portfolio with the issuance of our first pharmacokinetic patent, bolstering our protection, which is expected at least into 2037.

In addition to the progress on our pipeline, we built out the infrastructure to support to our evolution to a commercial-stage biopharmaceutical company. We made targeted investments in commercialization activities to ensure a successful product launch, including hiring field-based sales leadership and medical science liaisons. And we secured nearly $450 million in financing between a follow-on equity raise in the first quarter and a debt facility in the fourth quarter, ensuring that we can adequately fund both our ongoing clinical programs and the commercialization of roflumilast cream in plaque psoriasis.

These accomplishments have moved us closer to our goal of profoundly improving the lives of the millions of people who suffer from common dermatological diseases. While the introduction of new biologics in dermatology have helped to advance the treatment of people with serious skin diseases, there is still significant unmet need. Fewer than 10 percent of patients suffering from a chronic condition like psoriasis or atopic dermatitis have access to modern biologic therapies. Instead, they—and their physicians—must rely on outdated topical treatments, forcing suboptimal tradeoffs between efficacy, safety, and tolerability.

Arcutis is poised to transform this situation. Our industry-leading team of dermatology experts has built a robust pipeline of highly differentiated immuno-dermatology product candidates. These novel drugs have the potential to elevate the standard of care for common dermatological diseases and conditions, simplify disease management, and eliminate the need to make the clinical compromises demanded by current treatments.

Our progress has been driven by one of the leading dermatology teams in the industry, with six board-certified dermatology clinicians on staff, as well as medical dermatology's premier topical drug formulator. With deep experience in developing drugs and successfully bringing them to market, our team has collectively developed or commercialized more than 50 FDA-approved products.

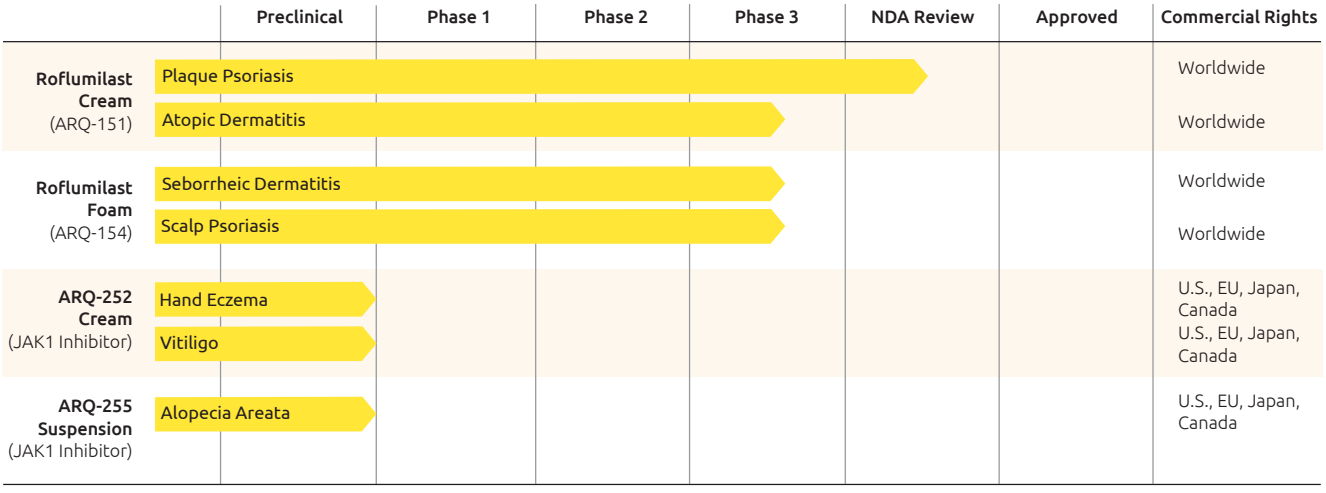
With respect to governance, our Board is demographically diverse (including three women directors) and highly independent, and that diversity also extends to background, experience, skills, and perspectives. Our commitment to diversity in clinical trials, our community outreach, and collective passion and drive to make a positive impact in the world have all contributed to the company's certification as a Great Place to Work. More importantly, it builds a world-class culture and makes Arcutis a company that we all are proud to be part of.

We expect 2022 to be a transformative year, and I couldn't be more optimistic about the future of Arcutis and the positive impact we can have on the lives of people suffering from these chronic dermatological diseases.

On behalf of Arcutis, its Board of Directors, and employees, thank you for your continued support. We look forward to updating you on our progress.

Frank Watanabe – President and Chief Executive Officer

Broad and Deep Pipeline - Multiple "Pipeline in a Molecule" Opportunities



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 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)

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**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by a check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

As of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1,082,483,639, based on the closing price of the registrant's common stock as reported on The Nasdaq Global Select Market.

The number of shares of the registrant's Common Stock outstanding as of February 16, 2022 was 50,380,254.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Proxy Statement for the registrant's 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K to the extent stated herein. The Proxy Statement will be filed within 120 days of the registrant's fiscal year ended December 31, 2021.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business” contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect”, and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- the success, cost, and timing of our plans to develop and commercialize immune-dermatology drugs, including our current products, roflumilast cream (ARQ-151), topical roflumilast foam (ARQ-154), ARQ-252 and ARQ-255 for indications including psoriasis, atopic dermatitis, scalp psoriasis, seborrheic dermatitis, hand eczema, vitiligo, and alopecia areata;
- the anticipated impact of the coronavirus disease 2019 (COVID-19) outbreak on our ongoing and planned clinical trials and other business operations, including any potential delays, halts, or modifications to our clinical trials and other potential changes to our clinical development plans or business operations;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals;
- future agreements, if any, with third parties in connection with the commercialization of our product candidates;
- the success, cost, and timing of our product candidate development activities and planned clinical trials;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the potential market size and the size of the patient populations for our product candidates, if approved for commercial uses;
- the potential U.S. market sales for our product candidates, if approved for commercial use;
- our commercialization, marketing, and manufacturing capabilities and strategy;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key management and technical personnel;
- our expectations regarding our ability to obtain, maintain, and enforce intellectual property protection for our product candidates; and
- our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in “Risk factors” and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this Annual Report on Form 10-K we have filed with the U.S. Securities and Exchange Commission (SEC) with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part I Item 1A. “Risk Factors” in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our 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;
- The terms of our loan and security agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business;
- 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 subject, and may prove difficult to meet in subjects 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 nonclinical 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 nonclinical 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.

TRADEMARKS

The mark “Arcutis” and the Arcutis logo are our registered trademarks, and all product names are our common law trademarks. All other service marks, trademarks, and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to herein appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

MARKET AND INDUSTRY DATA

This Annual Report on Form 10-K contains estimates, projections and other statistical data and information concerning our industry, our business, and the markets for our product candidates. Some data and statistical information contained herein, including market size and opportunity figures for our product candidates, are based on management’s estimates and calculations, which are derived from our review and interpretation of the independent sources, our internal research, and knowledge of the industry and market in which we operate. Some data and statistical information are based on independent reports from third parties, including DR/Decision Resources, LLC, or Decision Resources Group, and Adelphi Group Limited, or Adelphi Group, as well as reports that we commissioned from third parties. Decision Resources Group makes no representation or warranty as to the accuracy or completeness of the data, or DR Materials, set forth herein and shall have, and accept, no liability of any kind, whether in contract, tort (including negligence) or otherwise, to any third-party arising from or related to use of the DR Materials by us. Any use which we or a third-party makes of the DR Materials, or any reliance on it, or decisions to be made based on it, are the sole responsibilities of us and such third-party. In no way shall any data appearing in the DR Materials amount to any form of prediction of future events or circumstances and no such reliance may be inferred or implied.

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

Part I

Item 1. BUSINESS

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 drug development 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 advance our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success.

Our lead product candidate, roflumilast cream, has successfully completed pivotal Phase 3 clinical trials in plaque psoriasis, demonstrating symptomatic improvement and favorable tolerability in this population. We have submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), and the FDA has set a Prescription Drug User Fee Act (PDUFA) action date of July 29, 2022. Roflumilast is a highly potent and selective phosphodiesterase type 4, or PDE4, inhibitor, an established biological target in dermatology, with multiple PDE4 inhibitors approved by the FDA for the systemic treatment of 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 subjects, showing continued symptomatic improvement and favorable tolerability over a treatment period of 52 to 64 weeks. In atopic dermatitis, we have initiated three pivotal Phase 3 clinical studies: INTEGUMENT-1 and -2 are enrolling subjects six years of age or older and INTEGUMENT-PED is enrolling subjects between the ages of two and five years. We expect to provide topline data from each of INTEGUMENT-1 and -2 by the end of 2022. We intend to submit a supplemental New Drug Application (sNDA) for topical roflumilast cream for the treatment of atopic dermatitis patients aged six years or older in 2023 based on the results of INTEGUMENT-1 and -2. Due to the inherent challenges of enrolling young children in clinical trials, together with impacts on enrollment from COVID-19, we now expect to provide topline data from INTEGUMENT-PED in 2023. We intend to submit a subsequent sNDA for the younger age cohort based on INTEGUMENT-PED following the potential initial atopic dermatitis approval in patients aged six years or older.

We are also developing a topical foam formulation of roflumilast, and have successfully completed Phase 2 clinical trials in both seborrheic dermatitis and scalp and body psoriasis. In seborrheic dermatitis, we initiated a single pivotal Phase 3 clinical trial, with topline data anticipated in mid-year 2022. We also initiated a single pivotal Phase 3 clinical trial in scalp and body psoriasis, with topline data anticipated in the second half of 2022. If these pivotal Phase 3 trials for roflumilast foam are positive, we expect the data to be a sufficient basis for an NDA submission to the FDA for each indication.

Beyond topical roflumilast, we are developing ARQ-252, a potent and highly selective topical Janus kinase type 1, or JAK1, inhibitor. In May 2021, we announced that the Phase 2 study of ARQ-252 in chronic hand eczema did not meet its primary endpoint, with further analyses of the study pointing to inadequate local drug delivery to the skin. Given these analyses, we also elected to terminate the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment in vitiligo, as we began reformulation efforts to develop an enhanced formulation of ARQ-252 that delivers more active drug to targets in the skin. Additionally, we have formulation and nonclinical efforts continuing for ARQ-255, an alternative deep-penetrating topical formulation of ARQ-252 designed to reach deeper into the skin and hair follicle in order to potentially treat alopecia areata. The ARQ-255 formulation is separate and distinct from ARQ-252, and thus there are no implications to ARQ-255 from ARQ-252.

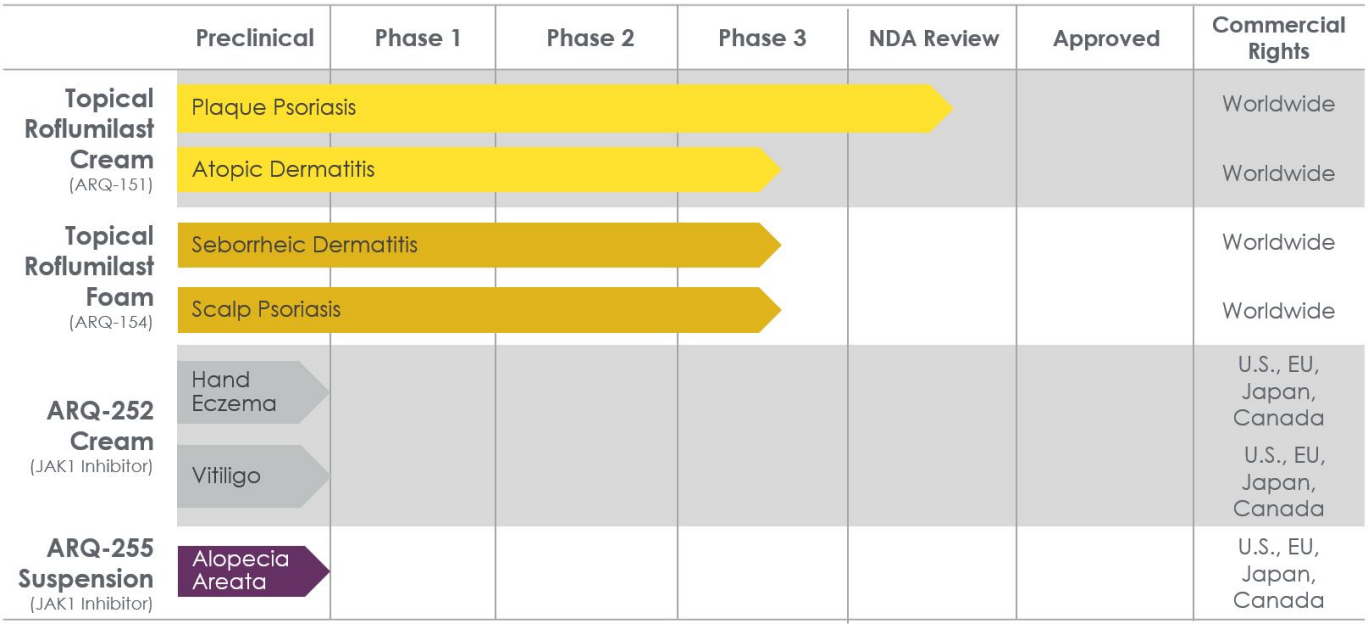
Dermatological diseases such as psoriasis, atopic dermatitis, seborrheic dermatitis, hand eczema, alopecia areata, and vitiligo affect hundreds of millions of people worldwide each year, impacting their quality of life, and physical, functional, and emotional well-being. There are many approved treatments for these conditions, but a large opportunity remains due to issues with existing treatments. Topical treatments are used for nearly all patients, but existing topicals are limited by one or more of the following: modest response rates, side effects, patient adherence, application site restrictions, and limits on duration of therapy. Topical corticosteroids, or TCS, are commonly used as the first-line therapy for the treatment of inflammatory skin conditions such as psoriasis, atopic dermatitis, and seborrheic dermatitis. While many patients see improvements, long-term TCS treatment carries the risk of a variety of significant side effects. As a result, TCS are typically used intermittently for brief periods, which can lead to disease flares when patients stop TCS therapy. In psoriasis, vitamin D analogs are also used, but have lower response rates than TCS and are frequently irritating. In atopic dermatitis, topical calcineurin inhibitors, or TCIs, and crisaborole (Eucrisa), a topical non-steroidal PDE4 inhibitor, are used, but have lower response rates than TCS and are associated with application site burning. TCIs also have a boxed warning for cancer risk. Topical ruxolitinib (Opzelura) was approved for the treatment of atopic dermatitis in September 2021, but carries an extensive boxed warning for numerous severe side effects, and is limited to short-term, intermittent use after failure of other treatments. In seborrheic dermatitis, in addition to TCS, topical antifungals are commonly used, but have limited efficacy.

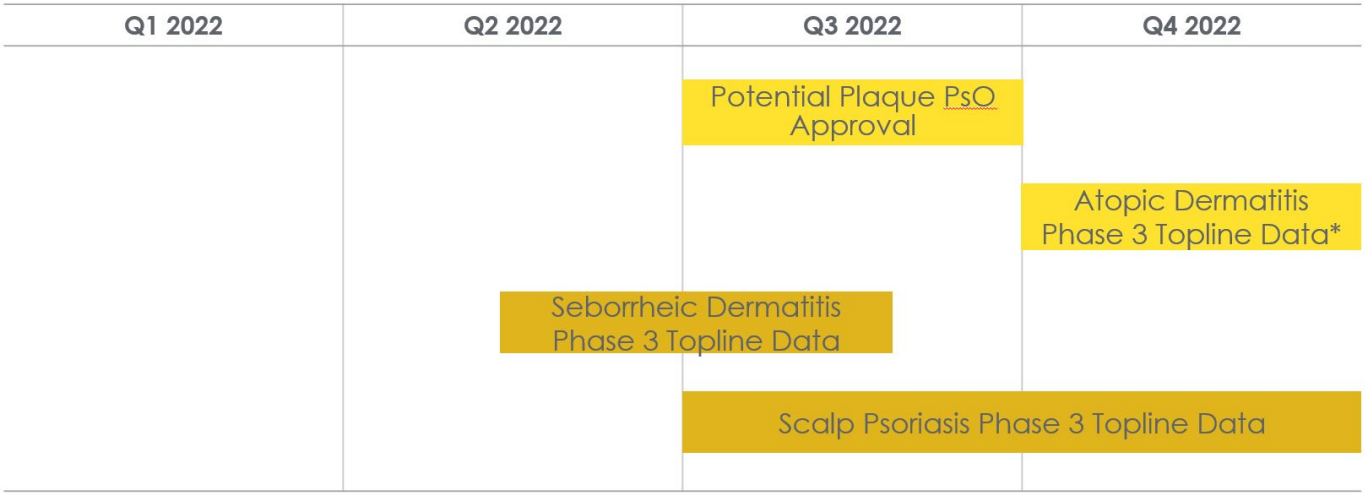
Biologic and systemic therapies are also available for some diseases, but are typically indicated for a small percentage of the affected population. Biologics for psoriasis and atopic dermatitis have shown impressive response rates but are only indicated for the minority of patients with moderate-to-severe forms of disease, are expensive, and often face reimbursement and access restrictions. Treatment with oral systemic therapies such as methotrexate and apremilast (Otezla) has also been limited given modest symptomatic improvement and the frequency of adverse events. Additionally, many patients on biologic and systemic therapies still require adjunctive topical therapy to treat residual symptoms.

Given the limitations associated with existing treatments, we believe patients with inflammatory skin conditions and their dermatologists are dissatisfied with their current treatment options. We believe that there is a significant opportunity to leverage developments in other fields of medicine, particularly inflammation and immunology, to address the significant need for effective chronic treatments in immuno-dermatology. Our initial focus is to address patients' significant need for innovative topical treatments that directly target molecular mediators of disease, have the potential to show significant symptomatic improvement, maintain a low risk of toxicity or side effects, and are suitable for chronic use on all areas of the body. Based on market research and our internal estimates, we estimate our primary addressable market opportunity, which focuses on U.S. patients treated by dermatologists with topical therapies, at 5 million patients across psoriasis, atopic dermatitis, and seborrheic dermatitis. There are millions of additional U.S. patients suffering from chronic hand eczema, vitiligo, and alopecia areata, as well as millions of patients treated by physicians other than dermatologists for their psoriasis, atopic dermatitis, and seborrheic dermatitis.

Our Pipeline

The following charts summarize our product pipeline and our upcoming anticipated milestones:





*Phase 3 topline for INTEGUMENT-1 and -2; INTEGUMENT-PED to follow in 2023

Our Strategy

Our strategy is to leverage recent innovations in inflammation and immunology to identify molecules against validated biological targets in dermatology, and to develop and commercialize best-in-class products based on those molecules that address significant unmet needs in immuno-dermatology:

Key elements of our strategy include:

- ***Rapidly develop and commercialize our lead product candidate, roflumilast cream, for the treatment of patients with plaque psoriasis and atopic dermatitis.*** Based on the clinical data generated to date, we believe roflumilast cream has the potential to be the best-in-class non-steroidal topical treatment, with symptomatic improvement in psoriasis patients similar to the combination of a high potency steroid and calcipotriene while potentially delivering a low risk of side effects and a favorable tolerability profile that enables chronic administration, including for pediatric patients. In plaque psoriasis, we have successfully completed pivotal Phase 3 clinical trials, as well as a long-term safety study. We have submitted an NDA to the FDA, and the FDA has set a PDUFA action date of July 29, 2022. In atopic dermatitis, we have initiated three pivotal Phase 3 clinical studies: INTEGUMENT-1 and -2 are enrolling subjects six years of age or older, and INTEGUMENT-PED is enrolling subjects between the ages of two and five years. We expect to provide topline data from each of INTEGUMENT-1 and -2 by the end of 2022. We intend to submit an sNDA for topical roflumilast cream for the treatment of atopic dermatitis patients aged six years or older in 2023 based on the results of INTEGUMENT-1 and -2. We expect to provide topline data from INTEGUMENT-PED in 2023 and submit a subsequent sNDA for the younger age cohort following the potential initial atopic dermatitis approval in patients aged six years or older.
- ***Expand our addressable market with roflumilast foam.*** We are developing a foam formulation of roflumilast for the treatment of scalp and body psoriasis and seborrheic dermatitis, diseases impacting hair-bearing areas of the body where a cream is not suitable. We have successfully completed Phase 2 clinical trials with roflumilast foam in both seborrheic dermatitis and scalp psoriasis, demonstrating promising efficacy and tolerability in both diseases. In seborrheic dermatitis, we initiated a single pivotal Phase 3 clinical trial, with topline data anticipated in mid-year 2022. We also initiated a single pivotal Phase 3 clinical trial in scalp and body psoriasis, with topline data anticipated in the second half of 2022. If these pivotal Phase 3 trials for roflumilast foam are positive, we expect the data to be sufficient basis for an NDA submission to the FDA for each indication.
- ***Establish an integrated development and commercial organization.*** We believe the concentrated prescriber base of the U.S. dermatology segment provides us with the opportunity to build a fully integrated commercial organization and targeted sales force for the commercialization of our product candidates among dermatology specialists. To further enhance the value of our product candidates, we may selectively seek partners to commercialize our products outside of the dermatology specialist segment, and to develop and commercialize our products outside of the U.S. market.
- ***Further expand our product portfolio through the development of ARQ-252/ARQ-255.*** We are developing ARQ-252 and ARQ-255, both of which contain a JAK1 inhibitor with a high relative selectivity to JAK1 over Janus kinase type 2, or JAK2, inhibitor for the treatment of chronic hand eczema and vitiligo, and potentially alopecia areata. Given its high relative selectivity to JAK1 over JAK2, we believe ARQ-252 and ARQ-255 have the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition, giving it the potential to be best-in-class. In May 2021, we announced that the Phase 2 study of ARQ-252 in chronic hand eczema did not meet its primary endpoint, with further analyses of the study pointing to inadequate local drug delivery to the skin. Given these analyses, we also elected to terminate the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment in vitiligo, as we began reformulation efforts to develop an enhanced formulation of ARQ-252 that delivers more active drug to targets in the skin. Our formulation and nonclinical efforts for ARQ-255, an alternative deep-penetrating topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata, are continuing. The ARQ-255 formulation is separate and distinct from ARQ-252, and thus there are no implications to ARQ-255 from ARQ-252.
- ***Leverage our product development platform to continue innovating and developing novel new treatments for dermatological diseases.*** Our expertise in dermatological clinical development and commercialization allows us to identify areas of high unmet needs, and our product development platform may allow us to develop novel new treatments that address those needs, as it has already with roflumilast cream, roflumilast foam, and ARQ-252/ARQ-255.

- ***Evaluate strategic opportunities to in-license best-in-class dermatology assets consistent with our core strategy.*** Leveraging our deep expertise in identifying promising drug candidates in dermatology, we will continue to seek best-in-class assets across treatment modalities directed against validated targets. We will continue to explore opportunities to in-license assets and develop them to address unmet medical needs in dermatology.

We believe one of our core strengths is that we have built the industry's leading platform for dermatology product development. This platform, coupled with our deep expertise in dermatology clinical development and commercialization, is the engine that allows us to generate our highly differentiated product candidates. Our platform has already generated several significant innovations, including:

- Our innovative topical formulation of roflumilast (patented)
- The pharmacokinetic characteristics relating to improving delivery and extending half-life of both the cream and foam formulations of topical roflumilast (patented)
- A novel topical cream without skin-drying surfactants (patent pending)
- The first topical treatment for seborrheic dermatitis with dual anti-fungal and anti-inflammatory action (patent pending)
- Our novel “4D” deep-penetrating formulation allowing topical delivery deeper in the dermis (patent pending).

Roflumilast Cream (ARQ-151)

Our lead product candidate, roflumilast cream, has the potential to offer symptomatic improvement in psoriasis patients similar to the combination of a high potency steroid and calcipotriene, a favorable tolerability profile, the ability to be used chronically, and little to none of the application site reactions associated with many existing topical treatments. Roflumilast cream is designed for simple once-a-day application for chronic use, does not burn or sting on application, and can be used on any part of the body, including sensitive or difficult-to-treat areas, such as the face and intertriginous regions. It quickly and easily rubs into the skin without leaving a greasy residue, does not stain clothing or bedding, or have an unpleasant smell. Roflumilast is a highly potent and selective PDE4 inhibitor that was approved by the FDA for systemic treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) in 2011. Roflumilast has demonstrated a potency advantage of approximately 25x to in excess of 300x compared to the active ingredients in the two other FDA-approved PDE4 inhibitors, Eucrisa and Otezla.

We are currently developing roflumilast cream for plaque psoriasis, including intertriginous psoriasis, as well as atopic dermatitis. We have successfully completed pivotal Phase 3 clinical trials, as well as a long-term safety study, in plaque psoriasis. We have submitted an NDA to the FDA, and the FDA has set a PDUFA action date of July 29, 2022. In atopic dermatitis, we completed our Phase 2 proof of concept study and initiated our Phase 3 clinical program. The atopic dermatitis Phase 3 program includes 4 studies: two identical studies with approximately 650 subjects each, ages 6 and above (INTEGUMENT-1 and -2); a study with approximately 650 subjects ages 2-5 (INTEGUMENT-PED); and an open label extension study with up to 1,500 subjects (INTEGUMENT-OLE). We expect to provide topline data from each of INTEGUMENT-1 and -2 by the end of 2022. We intend to submit an sNDA for topical roflumilast cream for the treatment of atopic dermatitis patients aged six years or older in 2023 based on the results of INTEGUMENT-1 and -2. We expect to provide topline data from INTEGUMENT-PED in 2023 and submit a subsequent sNDA for the younger age cohort following the potential initial atopic dermatitis approval in patients aged six years or older.

In July 2018, we executed a licensing agreement with AstraZeneca AB (AstraZeneca) for exclusive worldwide rights to roflumilast as a topical product in humans solely for dermatological indications. We have built our own intellectual property portfolio around topical uses of roflumilast, with issued and pending formulation, pharmacokinetic, and method-of-use patents in the United States and other jurisdictions from several distinct patent families, which should provide us with exclusivity for our product at least into 2037.

Plaque Psoriasis

Psoriasis Background

Psoriasis is an immune disease that occurs in about 3% of the U.S. population, representing approximately 8.6 million patients. About 90% of cases are plaque psoriasis, which is characterized by “plaques”, or raised, red areas of skin covered with a silver or white layer of dead skin cells referred to as “scale” (see figures below). Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and the plaques are often itchy and sometimes painful. At least 40% of plaque psoriasis patients have plaques on their scalp, about 15% have plaques in their intertriginous regions, approximately 10% have plaques on their face, and one in three has plaques on their elbows and knees. Each of these areas present a variety of treatment challenges which may be well suited to treatment with topical roflumilast.

Psoriasis patients are generally characterized as mild, moderate, or severe, with approximately 75% experiencing a mild to moderate form of the disease and 25% experiencing a moderate-to-severe form of the disease. Pruritus (itching) is a particularly common and bothersome symptom for patients, which can be severe and impact sleep patterns. In addition, patients with plaque psoriasis can suffer substantial psychosocial impacts from their disease and have a 50% greater chance of depression than the general population.

Figures: Plaque Psoriasis

Source: DermNet (right)

Current Psoriasis Treatment Landscape

The vast majority of psoriasis patients are treated with topical therapies, of which there have been no novel treatments approved in over 20 years. Despite their widespread use, existing topical therapies all possess substantial shortcomings:

- ***Topical steroids*** are associated with a number of side effects, including, among others, hypothalamic-pituitary-adrenal (HPA) axis suppression, skin atrophy (thinning), striae (stretch marks), and telangiectasia (spider veins). Some of these side effects are irreversible. Consequently, high potency topical steroids are not recommended for chronic use, and physicians generally will not prescribe them for treatment on the face or in the intertriginous regions.

Figures: Steroid-induced striae (left) and Steroid-induced skin atrophy (right)

Source: DermNet (right)

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

Because high potency steroids and combinations containing high potency steroids provide robust symptomatic improvement for psoriasis patients, most physicians initiate treatment for nearly all patients with them. However, due to the limitations on duration of treatment to between two and eight weeks, most physicians will switch the patient to a low- to mid-potency steroid or to a vitamin D analog to manage the patient's psoriasis chronically. These "step down" options provide less symptomatic improvement and are often irritating. Also, rebound is a known challenge with steroids, where psoriasis returns even worse than before steroid treatment. As a result, patients are constantly cycling between effective short courses of high potency steroids and less effective "step down" maintenance treatments.

Treatment with biologics remains highly restricted. In the United States, less than 20% of moderate-to-severe psoriasis patients (equivalent to 6% of all psoriasis patients) are on biologic therapy. The uptake of biologics has remained limited due to multiple factors, including the fact that they are indicated only for use in moderate-to-severe patients, their high cost and patient co-payments, reimbursement and access restrictions, perceived risk of side effects, and patient fear of injection.

Treatment with non-biologic systemic therapy, such as methotrexate or Otezla is also limited. According to Decision Resources Group, non-biologic systemic therapy represents approximately 8% of patients worldwide and 11% of patients in the United States. The use of methotrexate has declined due to concerns about side effects and mandatory routine monitoring. Otezla has a limited U.S. market share in part due to its high annual price relative to topical treatments, modest symptomatic improvement, and frequent adverse events.

Atopic Dermatitis

Atopic Dermatitis Background

Atopic dermatitis is the most common type of eczema, affecting approximately 26 million people in the United States. Atopic dermatitis is the most common skin disease among children, with prevalence steadily increasing from 8% to 12% in the last two decades. Atopic dermatitis is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms and legs, and the rash can cover significant areas of the body (see figures below). The rash causes significant pruritus (itching), which can lead to damage caused by scratching or rubbing and perpetuating an 'itch-scratch' cycle.

Figures: Atopic Dermatitis Lesions

Source: DermNet

Given the high proportion of pediatric patients, safety and tolerability of atopic dermatitis treatments is paramount. Atopic dermatitis imposes a substantial burden on the patient, parents, and family. Pediatric patients with atopic dermatitis can suffer from sleep disturbances, behavioral problems, irritability, crying, interference with normal childhood activities, and social functioning. Adults with atopic dermatitis also frequently suffer from sleep disturbances, emotional impacts, and impaired social functioning. Adults with atopic dermatitis also appear to be at a significantly increased risk of anxiety, depression, and suicidal ideation compared to the general population.

Current Atopic Dermatitis Treatment Landscape

The vast majority of atopic dermatitis patients are being treated with topical therapies, particularly low- to mid-potency topical steroids and TCIs, and these two classes of drugs constituted nearly all atopic dermatitis prescriptions in 2021. Despite their widespread use, existing topical therapies all possess substantial shortcomings:

- ***Topical steroids*** pose a particular concern in pediatric patients due to the risk of systemic absorption, and the consequent risk of HPA axis suppression, and potential developmental problems. Chronic use of topical steroids in atopic dermatitis patients is generally avoided. Many physicians are also reluctant to use steroids to treat atopic dermatitis on the face due to the increased risk of glaucoma and cataracts, or the diaper/groin region due to risk of skin thinning. There is also considerable concern among many parents about treating their children with steroids.
- ***Topical calcineurin inhibitors*** are generally seen as providing less symptomatic improvement than topical steroids and are also associated with some application site burning. In 2005 the FDA placed a boxed warning on the labels of both TCIs regarding a potential increased risk of cancers, especially lymphomas, associated with their use, which often creates significant parental resistance to their use.
- ***Eucrisa*** is a topical non-steroidal PDE4 inhibitor approved by the FDA in 2016. Despite initial interest among the physician community to adopt the product, its growth has been hampered by modest symptomatic improvement, frequent occurrences of application site burning and stinging, and disadvantaged reimbursement status compared to other atopic dermatitis treatments.
- ***Opzelura*** is a topical JAK inhibitor approved in September 2021 for the treatment of mild to moderate atopic dermatitis. The label carries an extensive boxed warning for serious infections, all-cause mortality, malignancy, major adverse cardiovascular events and thrombosis, and the product is limited to short-term, non-continuous use after failure of other treatments.

Treatment with biologics like Dupixent remains highly restricted. In the United States, less than 2% of all atopic dermatitis patients are on biologic therapy. The uptake of biologics has remained limited due to multiple factors, including the fact that they are indicated only for use in moderate-to-severe patients, their high cost and patient co-payments, reimbursement and access restrictions, and patient fear of injection.

Roflumilast Cream Clinical Development

Plaque Psoriasis

We have successfully completed the pivotal clinical studies of roflumilast cream in plaque psoriasis, and submitted an NDA to the FDA. The FDA has set a PDUFA action date of July 29, 2022. Our NDA submission is supported by the positive data from the pivotal Phase 3 clinical studies, DERMIS-1 and DERMIS-2, and our long-term Phase 2b open label study. In all trials, roflumilast cream was generally well-tolerated with a favorable safety and tolerability profile.

Key Completed Trials

ARQ-151-301 and 302 (DERMIS-1 and DERMIS-2 pivotal Phase 3 studies)

The DERMIS-1 and DERMIS-2 studies were identical pivotal Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which subjects age 2 years and above with mild, moderate, or severe chronic plaque psoriasis involving between 2% and 20% body surface area received 8 weeks of (i) roflumilast cream 0.3% once daily or (ii) matching vehicle once daily. DERMIS-1 enrolled 439 subjects and DERMIS-2 enrolled 442 subjects.

Results from the eight-week treatment period demonstrated statistically significant improvement compared to the matching vehicle on key efficacy endpoints. On the studies' primary efficacy endpoint of percentage of subjects achieving Investigator Global Assessment (IGA) success, which was defined as a score of "clear" or "almost clear" plus a 2-grade improvement from baseline at week 8, 42.4% of subjects treated with roflumilast cream achieved IGA Success, compared to 6.1% of subjects treated with vehicle ($p < 0.0001$) in DERMIS-1, and 37.5% of subjects treated with roflumilast cream achieved IGA Success, compared to 6.9% of subjects treated with vehicle ($p<0.0001$) in DERMIS-2. Roflumilast cream also demonstrated statistically significant improvements over vehicle on key secondary endpoints, including on Intertriginous IGA Success, Psoriasis Area Severity Index-75, reductions in itch as measured by the Worst Itch-Numerical Rating Scale, and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary (PSD).

Roflumilast cream was well-tolerated by the patient populations, with rates of treatment-emergent adverse events ("TEAEs") low and similar to vehicle, with most TEAEs assessed as mild to moderate in severity. Of the subjects treated with roflumilast cream, five subjects (1.7% of subjects) in DERMIS-1 and one subject (0.3% of subjects) in DERMIS-2 discontinued the study due to a TEAE. There were no treatment-related serious adverse events.

ARQ-151-202 (Long-Term Safety Study)

The long-term safety study was a Phase 2, multi-center, open label study of the long-term safety and efficacy of roflumilast cream 0.3% in adult subjects with chronic plaque psoriasis involving up to 25% total body surface area (BSA), evaluated in two cohorts: subjects who completed the ARQ-151-201 Phase 2b, randomized, controlled trial; and previously untreated subjects. All subjects applied roflumilast cream 0.3% once daily for 52 weeks at home. Approximately half (164 out of 332) of the subjects entered this long-term study after completing treatment with roflumilast cream 0.3% or 0.15% in the randomized Phase 2b study (ARQ-151-201) and therefore received up to 64 weeks of total treatment with roflumilast cream (12 weeks in the randomized Phase 2b study and 52 weeks in the long-term safety study). Periodic clinic visits included assessments for clinical safety, application site reactions, and disease improvement or progression. The primary outcome measures of this long-term safety study were the occurrence of TEAEs and the occurrence of serious adverse events.

In this open label study, roflumilast cream 0.3% applied once daily for up to 52 weeks demonstrated favorable safety and tolerability over the long-term treatment period, consistent with what was seen in the randomized Phase 2b study, with only 3.6% of subjects experiencing a treatment-related adverse event during 52 weeks of treatment. Additionally, a durable treatment effect was maintained through 52 to 64 weeks. At week 52 of the long-term safety study, 44.8% of all subjects attained an IGA Success of clear or almost clear, with 34.8% of subjects in Cohort 1 and 39.5% of subjects in Cohort 2 achieving IGA Success, defined as a score of clear or almost clear plus a 2-grade improvement from baseline. Additionally, of the subjects in the 12-week randomized Phase 2b study who were treated with roflumilast cream 0.3%, and who attained an IGA of clear or almost clear at 12 weeks in the first study, then continued on treatment in the long-term safety study, 66.7% had an IGA of clear or almost clear at the end of 64 weeks of treatment or their last visit. Of the 332 subjects in this study, 73.5% completed the full 52 weeks of open label treatment, with only 3.9% of subjects discontinuing the study due to an adverse event and less than 1% of subjects discontinuing due to lack of efficacy. There were no treatment related serious adverse events reported.

Atopic Dermatitis

Key Completed Trials

ARQ-151-212

The most recent study completed with roflumilast cream in atopic dermatitis was a multi-center, double-blind, vehicle-controlled proof of concept Phase 2 study, in which 136 adolescents (ages 12 and above) and adults with mild to moderate atopic dermatitis involving between 1.5% and 35% BSA were randomized across three arms to receive once daily topical applications for 4 weeks of: (1) roflumilast cream 0.15%, or (2) roflumilast cream 0.05%, or (3) vehicle. The goals of this small proof of concept study were to establish whether roflumilast cream provides a signal of potential symptomatic improvement in atopic dermatitis subjects, as well as to gain an understanding of its tolerability. Completion rates for the study were 98% in the roflumilast cream 0.15% arm, 91% in the roflumilast cream 0.05% arm, and 93% in the vehicle arm.

On the study's primary endpoint, the absolute change from baseline in the Eczema Area and Severity Index (EASI) Total Score after 4 weeks of once daily treatment, neither dose reached statistical significance versus vehicle, although roflumilast cream 0.15% showed a trend towards significance, with a mean improvement of 6.4 in subjects treated with roflumilast cream 0.15% compared to 4.8 in subjects treated with vehicle ($p = 0.097$). On the secondary endpoint of mean percent change from baseline on EASI, roflumilast cream 0.15% demonstrated a statistically significant improvement versus vehicle (72.3% versus 55.8%, $p = 0.049$). Efficacy was also observed at both doses as measured by EASI-75 (roflumilast cream 0.05%: 59.1% versus vehicle: 31.1%, $p = 0.009$ and roflumilast cream 0.15%: 52.3% versus vehicle: 31.1%, $p = 0.045$). On the Validated Investigator Global Assessment - Atopic Dermatitis (vIGA-AD), roflumilast cream 0.15% also demonstrated a statistically significant improvement versus vehicle in the percentage of subjects achieving clear or almost clear (roflumilast cream 0.15%: 52.3% versus vehicle: 31.1%, $p = 0.040$).

In this study, both doses of roflumilast cream were well-tolerated. 95% of subjects on active treatment completed the full study. The incidence of treatment-related TEAEs and application site reactions were low (< 5%) and similar between active treatment and vehicle. All TEAEs were mild to moderate in severity. Among subjects receiving roflumilast cream, there was only one serious adverse event (SAE), which was unrelated to treatment, and only one discontinuation due to a TEAE.

We believe the consistent evidence of improvement in atopic dermatitis signs and symptoms demonstrated by both strengths of roflumilast cream across multiple endpoints, as well as the magnitude of improvement demonstrated on both doses in this small proof-of-concept study, demonstrate the ability of roflumilast cream to effectively treat atopic dermatitis. Additionally, this study provided valuable insights into the safety and tolerability of roflumilast cream in this population, an especially important consideration because the majority of atopic dermatitis sufferers are young children. While the study did not reach statistical significance on every endpoint, the consistency of evidence for improvement in atopic dermatitis, coupled with favorable tolerability data, provides us with the confidence to continue the development of roflumilast cream in atopic dermatitis.

Key Ongoing Trials

The atopic dermatitis Phase 3 program includes four studies. INTEGUMENT-1 and -2 are multi-center, double-blind, vehicle-controlled Phase 3 studies, in approximately 650 subjects in each study, ages 6 and above with mild to moderate atopic dermatitis. Subjects have been randomized to receive once daily topical applications for 4 weeks of roflumilast cream 0.15%, or vehicle. The primary endpoint is the proportion of all randomized subjects who attain IGA Success, defined as a vIGA-AD score of 'clear' or 'almost clear' plus a 2-grade improvement from Baseline at week 4. Sharing a similar overall design, INTEGUMENT-PED is a multi-center, double-blind, vehicle-controlled Phase 3 study in approximately 650 subjects ages 2-5 with mild to moderate atopic dermatitis. Subjects have been randomized to receive once daily topical application for 4 weeks of roflumilast cream 0.05%, or vehicle and the primary endpoint is also the proportion of all randomized subjects who attain IGA Success at week 4. INTEGUMENT-OLE is an open label extension study that is enrolling up to 1,500 subjects who have completed INTEGUMENT-1, -2, or -PED. Subjects are to be treated for up to 52 weeks and the primary endpoints are the occurrence of TEAEs and SAEs. We expect to provide topline data from each of INTEGUMENT-1 and -2 by the end of 2022, and from INTEGUMENT-PED in 2023.

Roflumilast Foam (ARQ-154)

We are also developing a foam formulation of topical roflumilast for the treatment of scalp psoriasis and seborrheic dermatitis. Roflumilast foam contains the same highly potent and selective PDE4 inhibitor in roflumilast cream, and is nearly identical to roflumilast cream, with all ingredients in the foam being the same as those in the cream, other than reduced oil content and the addition of a propellant in the can to create the foam. Roflumilast foam is a light foam, similar to hair mousse, that has been designed to deliver the drug to the scalp while not leaving a greasy residue or disturbing hair style. The foam breaks easily upon agitation, creating a thin solution that can be rubbed easily into the scalp. Additionally, the product does not melt on the fingers prior to application. Roflumilast foam will not stain clothing or bedding, and does not have an unpleasant smell. Roflumilast foam is designed for simple once-a-day application and neither burns nor stings on application.

We have successfully completed Phase 2 studies of roflumilast foam in seborrheic dermatitis and scalp and body psoriasis, demonstrating promising efficacy and tolerability in both diseases, and are currently conducting pivotal Phase 3 studies in both indications. We believe that roflumilast foam may offer physicians and patients a highly differentiated clinical profile that is ideally suited to address unmet needs in the topical treatment of seborrheic dermatitis and scalp psoriasis.

Seborrheic Dermatitis

Seborrheic Dermatitis Background

Seborrheic dermatitis is a common skin disease that is estimated to occur in more than 10 million people in the United States. The disease causes red patches covered with large, greasy, flaking yellow-gray scales, and is frequently itchy. It appears most often on the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back as depicted in the figure below. A milder variant of the disease is dandruff. While the pathogenesis of seborrheic dermatitis is not well understood, some experts believe a contributor is an over-abundance of *Malassezia*, a naturally occurring yeast found on normal skin but found in excess numbers on skin with seborrheic dermatitis. There also is an immunological or inflammatory component, possibly as a result of the proliferation of the *Malassezia* yeast and its elaboration of substances that irritate the skin. Seborrheic dermatitis can occur in both adults and infants, and in infants is commonly referred to as "cradle cap".

Figures: Seborrheic Dermatitis

Current Seborrheic Dermatitis Treatment Landscape

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

- **Antifungal agents**, particularly azoles such as ketoconazole, are the cornerstone of therapy for seborrheic dermatitis. These agents are available in a variety of topical formulations, and oral antifungals are occasionally used in very severe cases. Antifungals in the treatment of seborrheic dermatitis are generally well-tolerated, although some patients experience irritant contact dermatitis, a burning or itching sensation, or dryness.
- **Topical steroids**, mostly low- to mid-potency, are often prescribed for patients suffering from seborrheic dermatitis because of the inflammatory component of the disease. Due to the risks associated with steroid use, particularly on the face, physicians try to limit duration or avoid steroid therapy.
- **TCIs** are also sometimes used off-label for the treatment of seborrheic dermatitis. These agents appear to provide symptomatic improvement in seborrheic dermatitis due to their anti-inflammatory effects. As previously noted, TCIs carry a boxed warning for the potential increased risk of cancers, especially lymphomas, associated with their use, and physicians generally try to avoid long-term use in patients suffering from seborrheic dermatitis. Additionally, TCIs only provide symptomatic improvement in seborrheic dermatitis in areas of skin that are very thin and where the drug can penetrate (i.e., largely the periocular areas only).

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

We believe roflumilast foam may present a unique dual mechanism of action to treat patients with seborrheic dermatitis. Based on clinical data to date across indications, topical roflumilast has demonstrated strong anti-inflammatory properties. In addition, a recent nonclinical study demonstrated that roflumilast foam may also possess anti-fungal effects, specifically against *Malassezia*, the fungus implicated in seborrheic dermatitis. Because the pathogenesis of seborrheic dermatitis potentially includes both a fungal overgrowth component and an inflammatory component, roflumilast foam's putative dual mechanism of action may provide symptomatic improvement for patients not achieving suitable responses from currently available therapies. In addition to the opportunity in treatment resistant patients, we believe roflumilast foam may be an option for some patients as a first-line therapy, especially patients with involvement of the face where other therapies are contraindicated.

Scalp Psoriasis

Scalp Psoriasis Background

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

Figures: Scalp Psoriasis

Source: DermNet (left)

Current Scalp Psoriasis Treatment Landscape

Scalp psoriasis treatments are similar to plaque psoriasis treatments, given that the plaques are identical to the plaques in other body areas. Topical treatments for scalp psoriasis include TCS, vitamin D analogs, or the combination, in a topical formulation suitable for hair-bearing areas, such as shampoos, solutions, or foams. However, many of the current topical formulations for hair-bearing areas are poorly formulated and are not well-received by patients. Existing topical treatments for the scalp also suffer from the same efficacy, safety, tolerability, and patient acceptability issues as existing creams and ointments. While both biologics and systemic treatments will improve scalp psoriasis, they suffer from the same limitations on their use as in plaque psoriasis.

Roflumilast Foam Clinical Development

We have successfully completed Phase 2 studies of roflumilast foam in seborrheic dermatitis and scalp psoriasis. In seborrheic dermatitis, we initiated a single pivotal Phase 3 clinical trial, with topline data anticipated in mid-year 2022. We also initiated a single pivotal Phase 3 clinical trial in scalp and body psoriasis, with topline data anticipated in the second half of 2022. If these pivotal Phase 3 trials for roflumilast foam are positive, we expect the data to be sufficient basis for an NDA submission to the FDA for each indication.

Seborrheic Dermatitis

Key Completed Trials

ARQ-154-203 (Phase 2 Study)

Study ARQ-154-203 enrolled 226 adult subjects with moderate-to-severe seborrheic dermatitis. This 8-week, multi-center, multi-national, double-blind, vehicle-controlled study evaluated the safety and efficacy of roflumilast foam 0.3% administered once daily to affected areas on the scalp, face, and body.

Roflumilast foam 0.3% administered once daily for 8 weeks demonstrated statistically significant improvement compared to a matching vehicle foam on key efficacy endpoints in subjects with moderate-to-severe seborrheic dermatitis. On the study's primary endpoint assessed at week 8, roflumilast foam 0.3% achieved an IGA Success rate of 73.8% compared to a vehicle rate of 40.9% ($p<0.0001$). IGA Success is defined as the achievement of an IGA score of 'clear' or 'almost clear' on a 5-grade scale plus at least a two-point change from baseline. The onset of effect was rapid, with roflumilast foam statistically separating from vehicle as early as week 2, the first visit after baseline, on IGA Success as well as multiple secondary endpoints. For example, at week 8, 64.6% of subjects treated with roflumilast foam who had a baseline WI-NRS score of 4 achieved an itch reduction of at least 4 points compared to 34.0% of vehicle treated subjects ($p=0.0007$). Other secondary endpoints included overall assessment of erythema and overall assessment of scaling, which also had positive outcomes.

Importantly, roflumilast foam was well-tolerated, with rates of application site adverse events, treatment-related adverse events, and discontinuations due to adverse events low and similar to vehicle. Only 2 out of 154 subjects (1.3%) treated with roflumilast foam discontinued the study due to an adverse event, compared to 1 out of 72 subjects (1.4%) treated with the vehicle.

Key Ongoing and Upcoming Trials

ARQ-154-304 (Phase 3 Study)

The "STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis" (STRATUM) is a Phase 3, parallel group, double blind, vehicle-controlled study of the safety and efficacy of roflumilast 0.3% foam administered once-daily in approximately 450 subjects ages nine and older with moderate to severe seborrheic dermatitis. The primary endpoint of the study is the proportion of subjects achieving IGA Success, defined as an IGA score of “clear” or “almost clear” plus a 2-point improvement at eight weeks.

ARQ-154-214 (Long-Term Safety)

Study ARQ-154-214 is an ongoing multi-center, open label Phase 2 long-term safety study of roflumilast foam 0.3% applied once daily in subjects with seborrheic dermatitis. This study includes subjects who were treated previously in the Phase 2 trial (ARQ-154-203), as well as subjects naive to treatment with roflumilast foam. Periodic clinic visits will include assessments for clinical safety, application site reactions, and disease improvement, or progression.

Scalp Psoriasis

Key Completed Trials

ARQ-154-204 (Phase 2b Study)

Study ARQ-154-204 was a multi-center, multi-national, double-blind, vehicle-controlled Phase 2b study, in which 304 adolescents (ages 12 and above) and adults with scalp psoriasis covering at least 10% of the total scalp involvement and up to 25% of total psoriasis involvement in all body areas were randomized to receive 8 weeks of (1) roflumilast foam 0.3% once daily, or (2) matching vehicle once daily. Randomization was 2:1, active to vehicle. The primary endpoint of the trial was achievement of a Scalp IGA (S-IGA) scale score of “clear” or “almost clear” plus a 2-grade improvement from baseline, or S-IGA, at week 8. Multiple secondary endpoints were also evaluated.

Roflumilast foam demonstrated statistically significant improvements compared to a matching vehicle foam on key efficacy endpoints. On the study’s primary endpoint of S-IGA Success assessed at week 8, roflumilast foam 0.3% achieved a rate of 59.1% compared to a vehicle rate of 11.4% ($p<0.0001$). Onset was rapid, with significantly higher rates of S-IGA Success noted as early as 2 weeks.

Multiple secondary endpoints were also met. On the key secondary endpoint of Body Investigator Global Assessment (B-IGA) success assessed at week 8, roflumilast foam 0.3% achieved a rate of 40.3% compared to a vehicle rate of 6.8% ($p<0.0001$), with separation from vehicle on B-IGA Success as early as 2 weeks. Symptomatic improvement was also demonstrated, with 71.0% of subjects treated with roflumilast foam 0.3% who had a baseline Scalp Itch Numeric Rating Scale score of 4 or greater achieving an itch reduction of at least 4 points at week 8 compared to 18.5% of vehicle treated subjects ($p<0.0001$).

Consistent with other clinical trials of topical roflumilast, roflumilast foam was well-tolerated, as evidenced by subject-reported local tolerability and rates of application site adverse events, treatment-related adverse events, and discontinuations due to adverse events low and similar to vehicle. Only 5 out of 200 subjects (2.5%) in the roflumilast foam treated group discontinued the study due to an adverse event, compared to 2 out of 104 subjects (1.9%) treated with the vehicle.

Key Ongoing and Upcoming Trials

ARQ-154-309 (Phase 3 Study)

The “A Randomized tRial Employing topiCal roflumilasT foam to treat scalp psORIasis” (ARRECTOR) study is a parallel group, double blind, vehicle-controlled pivotal Phase 3 study of the safety and efficacy of roflumilast 0.3% foam or a matching vehicle administered once-daily in approximately 420 subjects with scalp and body psoriasis ages 12 and older. The co-primary endpoints of the study include the proportion of subjects achieving S-IGA success and the proportion of subjects achieving B-IGA success, with IGA success defined as an IGA score of ‘clear’ or ‘almost clear’ plus a 2-point improvement from baseline after eight weeks.

ARQ-252

ARQ-252 is topical cream formulation of a potent and highly selective small molecule inhibitor of JAK1 that we are developing for chronic hand eczema and vitiligo. In a nonclinical study, ARQ-252 proved to be highly selective to JAK1 over JAK2. We believe that due to its high selectivity for JAK1 over JAK2, ARQ-252 has the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition. As the only JAK1-selective topical in development, we believe that ARQ-252 could offer a best-in-class topical JAK inhibitor, with a more favorable safety and tolerability profile than other topical JAK inhibitors due to its selectivity to JAK1 over JAK2, robust symptomatic improvement due to its high potency against JAK1, and a convenient and patient-friendly cream formulation.

In May 2021, we announced that the Phase 1/2b study of ARQ-252 in chronic hand eczema did not meet its primary endpoint, with further analyses of the study pointing to inadequate local drug delivery to the skin. Importantly, there were no safety or tolerability issues seen in that study. Given these analyses, we also elected to terminate the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment in vitiligo, as we began reformulation efforts to develop an enhanced formulation of ARQ-252 that delivers more active drug to targets in the skin. Additionally, we have formulation and nonclinical efforts continuing for ARQ-255, an alternative deep-penetrating topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. The ARQ-255 formulation is separate and distinct from ARQ-252, and thus there are no implications to ARQ-255 from ARQ-252.

In December 2019, we exercised our exclusive option under our Hengrui License Agreement to exclusively license the active pharmaceutical ingredient in ARQ-252 for all topical dermatological uses in the United States, Canada, Europe, and Japan. Jiangsu Hengrui Medicine Co., Ltd. (Hengrui) is developing SHR-0302, the active ingredient in ARQ-252, for the oral treatment of various inflammatory and immunological disorders, including rheumatoid arthritis, Crohn's disease, and ulcerative colitis, and has completed a Phase 2b study in rheumatoid arthritis. Under our agreement, we have the right to reference their safety data, along with the systemic toxicology data supporting their program. Hengrui has built strong intellectual property protection around the active ingredient in ARQ-252, and holds U.S. composition of matter patents, including patents for the bisulfate form of the active ingredient that do not begin to expire until 2033. We believe there is the potential for additional intellectual property protection of ARQ-252 through possible future formulation and other patents.

Chronic Hand Eczema

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

Hand eczema is a common, predominantly inflammatory, skin disease characterized variously by redness, fluid filled blisters or bumps, scaling, cracking, itching and pain occurring on the hands, especially the palms (see figures below). It is the most common skin disease affecting the hands, with prevalence estimated at up to 2.5% of the population. The impact of hand eczema on patients can be significant, leading to work absences or disability, social stigmatization, and psychosocial distress.

Figures: Hand Eczema

Current Hand Eczema Treatment Landscape

Hand eczema is a difficult disease to treat. The palms of the hand have skin that can be up to ten times thicker than skin from other body areas, which inhibits drug absorption and the ability to deliver drugs topically. Hand eczema is typically treated with high potency topical steroids, mostly due to the aforementioned skin barrier challenges. In some cases, physicians also will incorporate barrier creams to aid in hydration and to prevent the irritant effect caused by occupational exposure, a common cause of hand eczema. There are currently no FDA-approved treatments specifically for the indication of hand eczema. However, LEO Pharma has demonstrated proof of concept for their topical JAK inhibitor, delgocitinib, in Phase 2 studies. Physicians report that a significant percentage of patients, including up to 40% of patients with severe dyshidrotic eczema (one type of hand eczema), have an inadequate response to currently available treatments. In those who respond to high potency topical steroids, skin atrophy becomes a problem with chronic use, even on the thick skin of the palms.

Vitiligo

Vitiligo is a chronic and disfiguring autoimmune disease that causes the complete loss of skin color in blotches or patches, frequently in a symmetrical distribution, and has a significant impact on the patient's quality of life. The disease is caused by the localized destruction by the immune system of melanocytes, the skin cells that produce the skin pigment melanin, resulting in complete depigmentation in the affected area.

Vitiligo can have profound psychological impact on patients, particularly those with skin of color. Patients may feel loss of self-esteem and experience stigmatization. At this point in time, there are no FDA-approved treatments for vitiligo, so patients are often treated with off-label combinations of steroids, TCIs, ultraviolet light, and lasers. As such, there is great unmet need for therapies that are more effective and less limiting than currently available treatment modalities.

ARQ-252 Clinical Development

Chronic Hand Eczema

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

In May 2021, we announced that the Phase 1/2b study of ARQ-252 in chronic hand eczema did not meet its primary endpoint of IGA clear or almost clear at week 12, with further analyses of the study pointing to inadequate local drug delivery to the skin. Importantly, there were no safety or tolerability issues seen in that study. We are currently working on re-formulating ARQ-252 to develop an enhanced formulation that delivers more active drug to targets in the skin.

Vitiligo

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

Given the failure of the Phase 1/2b study of ARQ-252 in chronic hand eczema, and the data pointing towards inadequate drug delivery, we elected to terminate the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment in vitiligo. We are currently working on re-formulating ARQ-252 to develop an enhanced formulation that delivers more active drug to targets in the skin.

ARQ-255

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

Competition

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

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

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

For psoriasis, our primary competitors include injected biologic therapies such as Humira, marketed by AbbVie Inc. and Eisai Co., Ltd., and Enbrel, marketed by Amgen Inc.; Pfizer Inc., and Takeda Pharmaceutical Company Limited; non-injectable systemic therapies used to treat plaque psoriasis such as Otezla, marketed by 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 tapinarof, under development by Dermavant Sciences, Inc. and deucravacitinib, an oral Tyrosine kinase type 2 (Tyk2) inhibitor under development by BMS, Inc.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc.; Opzelura, marketed by Incyte Corporation; which was approved in September 2021, and generic and branded versions of low to mid-potency steroids such as hydrocortisone and betamethasone. In the moderate-to-severe setting, the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc; is approved, as well as the recently approved injectable biologic therapy Adbry, marketed by LEO Pharma. Non-injectable systemic therapies RINVOQ and CIBINQO were also recently approved in moderate-to-severe atopic dermatitis. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with roflumilast cream, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc. (approved as Corectim in Japan), topical PF-06700841, topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, oral PF-04965842, under development by Pfizer 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, under development by LEO Pharma A/S, which showed proof of concept in a Phase 2B trial.

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., Opzelura, 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: PF-6700841 and PF-06651600, under development by Pfizer, Inc., CTP-543, under development by Concert Pharmaceuticals, and baricitinib, under development by Eli Lilly and Company.

Commercial Operations

We intend to build our own commercial infrastructure in the United States and Canada to support the commercialization of our product candidates. We have begun to build commercial infrastructure given that regulatory approval of our first product candidate appears reasonably likely. We plan to build our own small specialty sales force to target dermatologists, with approximately 100 field-based staff. We may seek partnerships that allow us to target pediatricians and primary care physicians if required to maximize the potential of our product candidates. We have begun hiring the required sales, marketing, access and reimbursement, sales support, and distribution capabilities to prepare for commercialization. To develop the required commercial infrastructure, we will have to invest substantial financial and management resources, some of which will be committed prior to any confirmation that our product candidates will be approved, and we could invest resources and then later learn that a particular product candidate is not being approved. We may also seek other partners to help us access other geographic markets.

Intellectual Property

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

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

As of February 22, 2022, we own or have an exclusive license to 13 issued U.S. patents and 15 issued foreign patents, which include granted European patent rights that have been validated in various European Union (EU) member states, and 11 pending U.S. patent applications, 43 pending foreign patent applications and two applications filed under the Patent Cooperation Treaty. Of these patents and patent applications:

- **Roflumilast cream & roflumilast foam**: As of February 22, 2022, we own seven issued U.S. patents, one issued Canadian patent, one issued Japanese patent, one issued Chinese patent, one issued Hong Kong patent, seven pending U.S. patent applications, and 43 pending foreign applications (two in Canada; three each in Hong Kong, Japan, Mexico, New Zealand, India, Australia, Europe, Israel, Brazil, China, Korea and Eurasia; and five under the Patent Cooperation Treaty), relating to roflumilast cream and roflumilast foam. The issued U.S. patent that we have licensed from AstraZeneca claiming a composition of matter encompassing roflumilast, the active pharmaceutical ingredient in roflumilast cream and roflumilast foam, expired on January 27, 2020. Data exclusivity for oral roflumilast expired on January 23, 2021. Our issued patents relating to roflumilast cream and roflumilast foam contain claims directed to, among other things, formulating roflumilast in combination with hexylene glycol, methods of making such formulations, and methods of treatment using such formulations, and a method for improving treatment adherence by improving delivery and extending the plasma half-life of a roflumilast composition. These issued U.S. patents relating to roflumilast cream and roflumilast foam will expire not earlier than June 2037 (excluding any potential PTE). Our pending patents relating to roflumilast cream and roflumilast foam contain claims directed to, among other things, other aspects of our roflumilast formulations, as well as unique pharmacokinetic aspects of topical roflumilast.

- **ARQ-252 & ARQ-255**: As of February 22, 2022, we have an exclusive license from Hengrui to six issued U.S. patents, five issued Japanese patents, and five issued EU patents (validated in a number of EU member states, including for certain applications, Austria, Belgium, Bulgaria, Croatia, the Czech Republic, Estonia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxemburg, Monaco, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovenia, Slovakia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom), one pending U.S. patent application, three pending Japanese patent applications, and two pending EU patent applications relating to SHR0302. These patents and patent applications contain claims directed towards the composition of matter of the SHR0302 compound and bisulfate and crystalline forms thereof, pharmaceutical compositions and treatment methods. The issued patents and pending applications, if issued, relating to SHR0302 will not begin to expire until 2033. We have filed three pending U.S. patent applications and three patent applications under the Patent Cooperation Treaty relating to, among other things, SHR0302 formulations and methods of treatment. We anticipate filing additional patent applications directed towards formulations, methods and other aspects of our technology relating to ARQ-252 and ARQ-255 which we may develop in the future.

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

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

Exclusive License and Option Agreements

AstraZeneca

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

We paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of our Series B convertible preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product. We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specific regulatory approval milestones with respect to the AZ-Licensed Products, which includes $7.5 million upon FDA approval of our first product, and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates', and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on a AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country.

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

Jiangsu Hengrui Medicine Co., Ltd

In January 2018, we entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd, or Hengrui, whereby Hengrui granted us an exclusive option to obtain certain exclusive rights to research, develop, and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions, or the Field, in the United States, Japan, and the EU (including for clarity the United Kingdom), or the Territory.

In December 2019, we exercised our exclusive option, and also contemporaneously amended the agreement to expand the territory to additionally include Canada, and therefore now have a license from Hengrui under certain patent rights and know-how controlled by Hengrui to research, develop and commercialize products containing SHR0302 in the Field in the Territory. Such license is sublicensable through multiple tiers, exclusive as to the patent rights licensed from Hengrui and nonexclusive with respect to the know-how licensed from Hengrui, and does not extend to patent rights for improvements to SHR0302 which Hengrui may come to control in the future unless otherwise mutually agreed by the parties. In addition, we have sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products in the Field and in the Territory, at our sole cost and discretion, and shall use commercially reasonable efforts to (1) develop at least one licensed product and to (2) commercialize the licensed products following regulatory approval thereof. Pursuant to the Hengrui License Agreement, a joint coordination committee reviews the progress of development and commercialization of each parties' products containing SHR0302 in their respective territories and fields.

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

We made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui License Agreement option and license agreement. We also made a $1.5 million cash payment in connection with the exercise of our exclusive option. 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.

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

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. We, along with any third-party contractors, will be required to navigate the various nonclinical, clinical, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our products and product candidates. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's Good Laboratory Practice (GLP) requirements and other applicable regulations;
- submission to the FDA of an Investigational New Drug application (IND) which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (GCP) to establish the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice (cGMP) requirements to assure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality, and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

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

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

Clinical trials involve the administration of the investigational drug product to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with GCP requirements, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB for each site proposing to conduct each clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule, and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger Phase 3 clinical trials.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies, may be conducted after initial marketing approval, and may be used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, developers usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review and Approval Process

Assuming successful completion of the required clinical studies in accordance with all applicable regulatory requirements, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all nonclinical, clinical, and other testing, and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor of an approved NDA is also subject to an annual program fee. Waivers of application user fees may be obtained in certain limited circumstances.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for review, or "filed" by FDA, based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the additional information must be included in any resubmitted NDA, which is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the PDUFA guidelines that are currently in effect, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity (NME), and of ten months from the date of NDA receipt to complete a standard review of an NDA for a drug that is not an NME. These review periods may be reduced from ten months to six months for an application designated for priority review.

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

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it determines the facility is compliant with cGMP requirements and adequate to assure consistent production of the product within required specifications.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will typically issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may include limitations on the indicated uses for which such product may be marketed. For example, as a condition of approving an NDA, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the

benefits of the drug outweigh the potential risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicine by managing its safe use, and can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and the labeling and prescribing information for the product may be changed based on the results of these post-marketing studies.

Changes to the conditions established in an approved NDA, including changes in indications, labeling, or manufacturing processes or facilities, require a submission to the FDA in the form of an NDA supplement or as part of the NDA Annual Report. FDA approval prior to implementation is required for most major changes, and the FDA's timeline for review varies according to the type of change being made. An NDA supplement for a new indication typically requires clinical data, and the FDA uses the same general procedures when reviewing such NDA efficacy supplements as it does in reviewing original NDAs.

Pediatric Information

The Pediatric Research Equity Act (PREA) as amended, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required clinical assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of required pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. In addition, the Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six month extension of any exclusivity—patent or nonpatent—for a drug, if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new product candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during development and, once an NDA is submitted, the product candidate may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. There also are continuing, annual program fee requirements for any marketed products.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning, or other safety information about the product;
- fines, warning letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension, or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

The Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. However, a drug must meet certain criteria relative to the Listed Drug to be eligible to use the Section 505(b)(2) pathway as opposed to the abbreviated NDA, or ANDA pathway, which is described below. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an ANDA. An ANDA generally provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics, and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include nonclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or a Section 505(b)(2) NDA.

Upon submission of an ANDA or Section 505(b)(2) NDA, the applicant must certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The applicant may also elect to submit a statement certifying that its proposed label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the application until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Hatch-Waxman Exclusivity

The Hatch-Waxman Act establishes a period of regulatory exclusivity for certain approved drug products during which the FDA cannot accept for review an ANDA or 505(b)(2) NDA that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon NDA approval of a drug containing a new chemical entity, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another applicant that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval.

Five year and three year exclusivity will not delay the submission or approval of a full 505(b)(1) NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes, and other healthcare laws and regulations.

The U.S. federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to commit a violation.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, a violation of the U.S. federal Anti-Kickback Statute can serve as a basis for liability under the federal False Claims Act. The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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 commit a violation.

In addition, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. Entities that are found to be in violation of HIPAA, as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

Further, the Physician Payments Sunshine Act requires certain manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians (defined broadly to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse-midwives) and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Compliance with these laws is difficult and time-consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any new therapeutic product candidate. Sales in the United States will depend in part on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE, and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which reimbursement for therapeutic product candidates may be sought can be subject to challenge, reduction, or denial by payors.

The regulations that govern coverage, pricing, and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, a drug company can obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of that product.

A drug company's ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, and other organizations. Even if one or more products are successfully brought to the market, these products may not be considered cost-effective, and the amount reimbursed for such products may be insufficient to allow them to be sold on a competitive basis. Increasingly, third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Significant delays can occur in obtaining reimbursement for newly-approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers a drug company's costs, including research, development, manufacture, sale, and distribution.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals, may need to be conducted. Third-party payors may not consider products to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable maintenance of price levels sufficient to realize an appropriate return on a drug company's investment in drug development.

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover a drug company's costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services, and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Affordable Care Act (ACA) was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs, (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, which has since been increased to 70%, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program, (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research, and (ix) established a Center for Medicare Innovation at Centers for Medicare and Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market, and sell any products we may develop.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, the probability of success of these and any other Trump administration reform initiatives is uncertain, particularly in light of the new Biden administration. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations. Further, it is possible that additional governmental action is taken in response to the evolving effects of the COVID-19 pandemic. Additionally, health reform initiatives may arise in the future, particularly as a result of the 2020 presidential election.

Human Capital Resources and Employees

As of December 31, 2021, we had 147 full-time employees. Of these full-time employees, 25 have an M.D., a Ph.D. or a Pharm. D and 3 have been Nurse Practitioners or Physician Assistants. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain, and motivate selected employees through the granting of stock-based compensation awards and cash-based performance bonus awards.

The pharmaceutical development business is fundamentally a people-centric, knowledge-based business. Additionally, one core element of our corporate strategy is to build an industry-leading team of dermatology experts. As such, we expend considerable management time and attention, and financial resources, to attracting, retaining, and motivating exceptional individuals at our company. These efforts include not only our recruitment and compensation programs, but equally importantly, include the corporate culture that we have built at the company, and the management practices we employ in order to obtain the best possible performance from our team.

Financial Information About Segments

We view our operations and manage our business as one reportable segment. See Note 1 in the Notes to Financial Statements included in this Annual Report on Form 10-K. Additional information required by this item is incorporated herein by reference to Part II, Item 6, “Selected Financial Data.”

About Arcutis Biotherapeutics

We were formed under the laws of the State of Delaware in June 2016 under the name Arcutis, Inc. and changed our name to Arcutis Biotherapeutics, Inc. in October 2019. Our principal executive offices are located at 3027 Townsgate Road, Suite 300, Westlake Village, California 91361, and our telephone number is (805) 418-5006. Our website address is www.arcutis.com. The information found on or accessible through our website is not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

Available Information

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended, and we therefore file periodic reports, proxy statements, and other information with the SEC relating to our business, financial statements, and other matters. The SEC maintains an Internet site, www.sec.gov, that contains reports, proxy statements, and other information regarding issuers such as Arcutis Biotherapeutics, Inc.

For more information about us, including free access to our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, visit our website, www.arcutis.com. The information found on or accessible through our website is not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

Item 1A. RISK FACTORS

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations". 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 nonclinical studies, conducting clinical trials for our product candidates, and preparing for commercialization activities.

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 or conduct sales and marketing activities necessary for successful commercialization.

Our net loss for the years ended December 31, 2021 and 2020 was approximately $206.4 million and $135.7 million, respectively. As of December 31, 2021, we had an accumulated deficit of $408.3 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to prepare for commercialization activities, 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 nonclinical 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 nonclinical 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 December 31, 2021, we had capital resources consisting of cash, cash equivalents, and marketable securities of $387.1 million. In addition, as of December 31, 2021, we had $75.0 million outstanding under our Loan Agreement and an aggregate of up to $150.0 million in additional funding under our loan and security agreement that may become available subject to the satisfaction of specified conditions. Based on our planned operations, we believe that our existing cash, cash equivalents, and marketable securities, combined with committed funding under the Loan Agreement, will be sufficient to fund our operations into 2024. 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 nonclinical studies and clinical trials, in particular our planned or ongoing clinical studies of roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast foam in seborrheic dermatitis and scalp and body psoriasis, ARQ-252 in chronic hand eczema and vitiligo, and our formulation and nonclinical efforts for ARQ-255 in alopecia areata;
- suspensions or delays in the enrollment, issues with data collection, or changes to the number of subjects we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic, competing trials or otherwise;
- 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, nonclinical 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 nonclinical 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, in light of the COVID-19 pandemic, competing trials or otherwise;
- 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) to help manage our clinical trials, 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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K should not be taken as indicative of our ability to grow our business.

The terms of our loan and security agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

As of December 31, 2021, we had $75.0 million outstanding under our loan and security agreement, or the Loan Agreement, with SLR Investment Corp., or SLR, and the lenders party thereto. Pursuant to the Loan Agreement, the lenders agreed to extend us term loans in an aggregate principal amount of up to $225.0 million, comprised of: (i) a tranche A term loan of $75.0 million, (ii) a tranche B-1 term loan of $50.0 million, (iii) a tranche B-2 term loan of up to $75.0 million, available in minimum increments of $15.0 million, and (iv) a tranche C term loan of up to $25.0 million. We refer to the tranche A, tranche B and tranche C term loans together as our Term Loans. As security for the obligations under the Loan Agreement, we granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of our assets, including our intellectual property, subject to certain exceptions. The Loan Agreement contains a number of representations and warranties and affirmative and restrictive covenants, including financial covenants, and the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry, or take future actions. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness."

If the debt under the Loan Agreement were accelerated due to an event of default or otherwise, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition. If we do not have or are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern. Moreover, regardless of a

potential event of default, the debt under the Loan Agreement matures and is due on January 1, 2027. As a result, we may need to refinance or secure separate financing in order to repay amounts outstanding when due, however, no assurance can be given that an extension will be granted, that we will be able to renegotiate the terms of the agreement with the lender or that we will be able to secure separate debt or equity financing on favorable terms, if at all.

In order to service our indebtedness, we need to generate cash from our operating activities or additional equity or debt financing. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

Risks Related to Development and Commercialization

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

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

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our nonclinical 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 competitive trials, 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, 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, particularly in light of the challenges to sales, marketing, and commercialization activities resulting from the COVID-19 pandemic;
- 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, including the impact on our business resulting from the COVID-19 pandemic, 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 nonclinical 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 nonclinical 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 subjects and did not reach statistical significance for the primary endpoint of absolute change in EASI. However, this study did provide evidence that roflumilast cream could provide symptomatic improvement, with statistically significant difference from vehicle on several key secondary endpoints, and a favorable tolerability profile in adults with atopic dermatitis and, following an End of Phase 2 meeting with the FDA in September 2020, we omitted our previously planned Phase 2b study in that indication and recently initiated Phase 3 clinical trials. Additionally, our Phase 1/2b clinical study of ARQ-252 for the treatment of chronic hand eczema did not meet its primary end point of IGA clear or almost clear at week 12 and we terminated our Phase 2a clinical trial evaluating ARQ-252 as a potential treatment for vitiligo. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical 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, competing trials, or otherwise;
- regulators or independent 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 subjects 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, 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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. 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 nonclinical 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 nonclinical 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 nonclinical or clinical studies. These setbacks have been caused by, among other things, nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

We currently have no products approved for sale. In September 2021 we submitted our first NDA to the FDA for our lead product candidate, roflumilast cream, and our other product candidates remain in clinical development. Significant risk remains and we cannot provide assurance that our product candidates 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 nonclinical 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 nonclinical 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 nonclinical 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 FDA may delay consideration of our sNDA for roflumilast for the treatment of atopic dermatitis until the results of the pediatric trial (INTEGUMENT-PED) are included in the submission;
- 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 nonclinical 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.

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 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, 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 and preliminary 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 and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects.

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

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

Certain of our primary and secondary endpoints in our clinical trials, including our Phase 3 clinical trials of roflumilast cream in plaque psoriasis, and our previous and planned clinical trials in atopic dermatitis, vitiligo, chronic hand eczema, scalp and body psoriasis and seborrheic dermatitis involve subjective assessments by physician and subjects, which can increase the uncertainty of clinical trial outcomes. For example, one of the secondary endpoints requires subjects 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 subjects.

Further, different results may be achieved depending upon the characteristics of the population enrolled in our studies and which analysis population is used to analyze results. For example, the primary endpoint in our Phase 3 clinical trials of roflumilast cream in plaque psoriasis and atopic dermatitis as well as our Phase 3 clinical trials of roflumilast foam in seborrheic dermatitis and scalp and body psoriasis is based on the percentage of subjects 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 subjects 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 subjects 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, timely enroll or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, for reasons which include the COVID 19 pandemic and those listed below. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as our product candidates, and subjects 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 subjects adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective subjects.

Furthermore, any negative results that we may report in nonclinical 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 subjects 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. In addition, it may be more challenging to identify and enroll certain patient populations or groups, such as pediatric patients. We have experienced enrollment delays in our INTEGUMENT-PED pediatric trial. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, including as a result of launching additional clinical sites, 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 nonclinical studies or clinical trials of these or future product candidates, if any, serious adverse events, unacceptable levels of toxicity, undesirable side effects or unexpected characteristics may emerge, causing us to abandon these product candidates or limit their development to more narrow uses, lower potency levels or subpopulations in which the serious adverse events, unacceptable levels of toxicity, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective.

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

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

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

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

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

Obtaining marketing approval for a product candidate is a complicated process. Although members of our management team have participated in pivotal trials and obtained marketing approvals for product candidates in the past while employed at other companies, we as a company have limited experience doing so. As a result, the approval process and related activities may require more time and cost more than we anticipate, and we may be unable to successfully complete them for any of our product candidates.

To date, we have submitted an NDA and have completed two Phase 3 studies and three Phase 2 studies in plaque psoriasis with roflumilast cream, a Phase 2 study in atopic dermatitis with roflumilast cream, and two Phase 2 studies in seborrheic dermatitis and scalp and body psoriasis with roflumilast foam. We also have pivotal Phase 3 clinical trials underway of roflumilast cream for the treatment of atopic dermatitis and of roflumilast foam in seborrheic dermatitis and scalp and body psoriasis. Failure to successfully complete, or delays in, our pivotal trials or related regulatory submissions would prevent us from or delay us in obtaining regulatory approval for our product candidates. In addition, it is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our applications that they are insufficient to obtain marketing approval of our product candidates. While the FDA encouraged us at our atopic dermatitis End of Phase 2 meeting to generate additional clinical data in adolescents and adults on the two roflumilast cream doses studied in our Phase 2 study, they also did not raise objections to us proceeding into Phase 3. If the FDA does not accept our applications or issue marketing authorizations for our product candidates, it may require that we conduct additional clinical, nonclinical, 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;
- any restrictions on the use of any of our product candidates; and
- the impact on our business, including our sales, marketing and commercialization activities, of the COVID-19 pandemic and the impact of the pandemic on physicians' practices and their ability to see patients and prescribe our products.

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 have begun to build our commercial infrastructure and plan to build a dermatologist-focused sales, distribution, and marketing infrastructure to market our product candidates in North America. We have begun hiring in areas to prepare for commercialization, including in sales management, sales representatives, marketing, access and reimbursement, sales support, and distribution. 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 or negatively affect the success of 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, which includes $7.5 million upon FDA approval of our first product, and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country.

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

There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. Furthermore, if we are forced to raise additional funds, we may be required to delay, limit, reduce, or terminate our product development or future commercialization

efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves. If we are unable to raise additional funds or maintain sufficient liquidity to make our payment obligations if and when they become due, including payment obligations under the license agreement with AstraZeneca and under the option and license agreement with Hengrui, we may be in material breach of our agreements and our counterparties may seek legal action or remedies against us (including by seeking to terminate the relevant agreements), which would harm our business, financial condition, results of operations, and prospects.

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

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

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

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

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

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., Opzelura, marketed by Incyte Corporation, was approved in September 2021, and generic and branded versions of low to mid-potency steroids such as hydrocortisone and betamethasone. In the moderate-to-severe setting, the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc. is approved, as well as the recently approved injectable biologic therapy Adbry, marketed by LEO Pharma. Non-injectable systemic therapies RINVOQ and CIBINQO were also recently approved in moderate-to-severe atopic dermatitis. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with roflumilast cream, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc. (approved as Corectim in Japan), topical PF-06700841, topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, oral PF-04965842, under development by Pfizer Inc., and injectable lebrikizumab, under development by Eli Lilly and Company.

For chronic hand eczema, our primary competitors include topical therapies such as branded and generic versions of clobetasol, such as Clobex, and generic versions of betamethasone dipropionate. The only other prescription product candidate we are aware of under development for the treatment of chronic hand eczema that would compete with ARQ-252 is delgocitinib, which recently showed proof of concept in a Phase 2a trial and has been approved in a different formulation in Japan (Corectim).

For vitiligo, our primary competitors include topical therapies such as generic and branded versions of calcineurin inhibitors, including Elidel, marketed by Bausch Health; branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat vitiligo and compete with ARQ-252, including but not limited to: topical cerdulatinib, under development by Dermavant Sciences, Inc., Opzelura, 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 subjects available to us to participate in clinical trials, because some subjects 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 have a competitive product profile or 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 candidates;
- 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 December 31, 2021, we had 147 full-time employees. We will need to continue to expand our managerial, clinical, commercial, operational, financial, and other resources in order to manage our operations and clinical trials, continue our development activities, and commercialize our lead product candidates or any future product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could undermine the credibility of our operating results, harm investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, our management is required to report upon the effectiveness of our internal control over financial reporting and, as we are no longer an emerging growth company, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting beginning with this Annual Report on Form 10-K. The rules governing the standards that must be met for our management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. In connection with our and our independent registered public accounting firm’s evaluations of our internal control over financial reporting, we may need to upgrade our systems, including information technology; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us or our independent registered public accounting firm conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002 may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third-party litigation, as well as investigations by the SEC, the stock exchange on which our securities are listed, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages, or other remedies.

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

We and the manufacturers of our products rely on suppliers of raw materials used in the production of our products. Some of these materials are available from only one source. If there is a disruption to one or more of our third-party suppliers' relevant operations, we will have no other means of producing our lead product candidates until they restore the affected facilities or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our nonclinical 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 nonclinical 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 nonclinical 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 nonclinical 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 roflumilast cream, 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 operations of our contract manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

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

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

Risks Related to Intellectual Property

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

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

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

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

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

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any, over such aspects of our technology. Even if patents do successfully issue covering such aspects

of our technology, third parties may design around or challenge the validity, enforceability, or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated, or held unenforceable. If the breadth or strength of protection provided by the patents we own or license with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidates. Even if the patent applications that we own or license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drugs in a non-infringing manner.

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

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. Our issued U.S. patents relating to roflumilast cream and roflumilast foam with claims directed to, among other things, formulating roflumilast in combination with hexylene glycol and pharmacokinetic properties of topical roflumilast for improving delivery and extending half-life are currently projected to expire on June 7, 2037 and August 25, 2037, and the issued U.S. patents which we have exclusive rights to from Hengrui as a result of the exercise of our exclusive option with Hengrui in December 2019 for the amount of $1.5 million cash, related to the composition of matter of the active ingredient in ARQ-252 and ARQ-255 (or bisulfate or crystal forms thereof) are currently projected to expire between January 21, 2033 and October 15, 2035 unless a PTE is granted. Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants, and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers, and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If

trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

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

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

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

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

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

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

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

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

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

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

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

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, product candidates, and our target indications. Our issued U.S. patents, with claims directed to roflumilast formulations with reduced crystal growth, encompassing roflumilast cream and pharmacokinetic properties of topical roflumilast for improving delivery and extending half-life are currently projected to expire on June 7, 2037 and August 25, 2037. Certain issued U.S. patents that we have licensed from Hengrui relating to, among other things, treatment of several diseases or disorders, including various cancers, allograft rejection, graft versus host disease, rheumatoid arthritis, atopic dermatitis, and psoriasis with SHR0302, or bisulfate and crystal forms thereof, are currently projected to expire beginning in 2033. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

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

extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and noncclinical 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 U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. 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 U.S. 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 U.S. 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 U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. Having a mandatory nonexclusive license grant may diminish the value of our patents as well as making it more difficult to protect our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

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 FDA 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, 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 COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of December 2021, and the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. 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.

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), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives) and teaching hospitals, the ownership and investment interests held by such physicians and their immediate family members;

- 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. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

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, 2022; 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 United States, 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

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. For example, our current Loan Agreement prohibits us from incurring certain additional indebtedness without the consent of our lender and restricts out ability to pay 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 $100.0 million, through an ATM equity offering program under which Cowen will act as our sales agent. During the year ended December 31, 2021, we did not issue or sell any shares of our common stock through our ATM program. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of approximately 10.6 million shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. In December 2021, our board of directors approved an employment inducement incentive plan with 1,250,000 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, RSU awards, and other stock-based awards. We plan to register all of the shares under the employment inducement incentive plan. Once we register the shares described in the paragraph above, such shares 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.

As of December 31, 2021, we had net operating loss (NOL) carryforwards available to reduce future taxable income, if any, for federal, California and other state income tax purposes of approximately $361.3 million, $360.1 and $5.3 million, respectively. If not utilized, state NOL carryforwards will expire beginning in 2030. Of the federal NOL, $3.5 million originated before the 2018 tax year and will expire beginning in 2036. Under the Tax Act and Jobs Act of 2017, the remaining $357.8 million of federal NOL carryforwards generated after December 31, 2017 will carryforward indefinitely. As of December 31, 2020, we had federal and California research and development tax credit carryforwards of $10.8 million and $2.4 million, respectively. If not utilized, the federal research and development tax credit carryforwards will begin to expire in 2036. The California research and development tax credit carryforwards are available indefinitely.

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

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

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

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

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

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

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. In addition, the terms of our Loan Agreement restrict our ability to pay dividends to limited circumstances. 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 and regional economic, political and health 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 global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease, such as COVID-19, and other unexpected events could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to clinical enrollment, clinical site availability, patient accessibility, conduct of our clinical trials and commercialization activities, as well as temporary closures of our facilities and the facilities of suppliers or contract manufacturers in the biotechnology supply chain. The COVID-19 outbreak, including developments involving subsequent COVID-19 variants, has already significantly affected the financial markets of many countries and has resulted and may in the future result in a variety of federal, state and local orders, guidance and restrictions. 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, including our commercialization activities.

A severe or prolonged economic downturn, political disruption or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

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

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

- limited daily trading volume resulting in the lack of a liquid market;
- the development status of our product candidates, including whether we discontinue development or if any of our product candidates receive regulatory approval;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- regulatory, legal or political developments in the United States and foreign countries;
- the results of our clinical trials and nonclinical 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 nonclinical 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 is influenced by the research and reports that industry or securities analysts publish about us or our business. 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. 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 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our corporate headquarters is located in Westlake Village, California, where we lease approximately 22,643 square feet of office space.

Item 3. 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 4. MINE SAFETY DISCLOSURES

None.

Part II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information for Common Stock

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol “ARQT” since the commencement of our IPO on January 31, 2020. Prior to that time there was no public market for our common stock.

Holders

As of February 16, 2022, there were approximately 21 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Dividend Policy

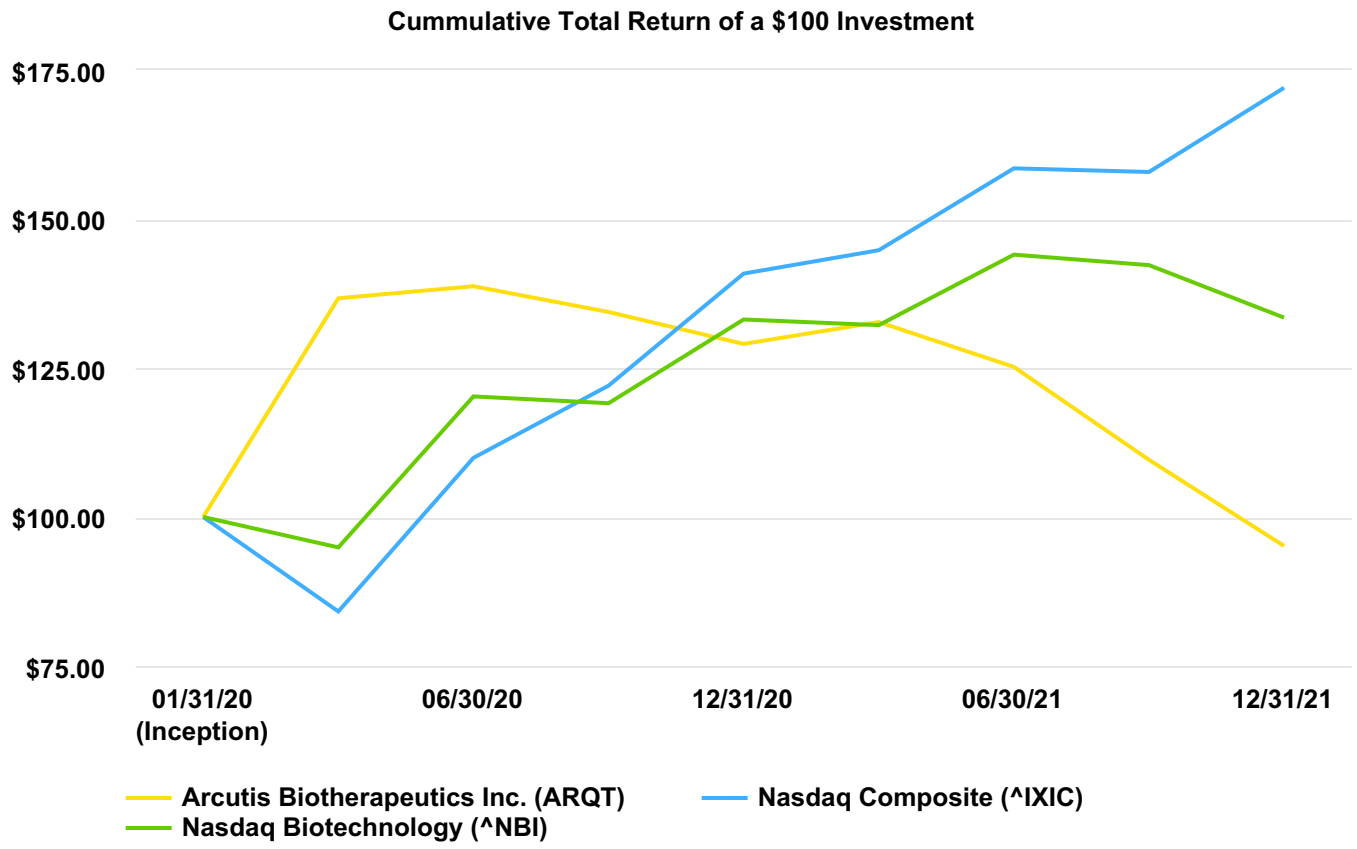
We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination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

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item with respect to our equity compensation plans is incorporated by reference to our definitive proxy statement relating to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates, or the Proxy Statement.

Stock Performance Graph

The graph below shows a comparison, from January 31, 2020 (the date our common stock commenced trading on Nasdaq) through December 31, 2021, of the cumulative total return to stockholders of our common stock relative to the Nasdaq Composite Index ("^IXIC") and the Nasdaq Biotechnology Index ("^NBI"). The graph assumes that $100 was invested in each of our common stock, the Nasdaq Composite and the Nasdaq Biotechnology at their respective closing prices on January 31, 2020 and assumes reinvestment of gross dividends. The stock price performance shown in the graph represents past performance and should not be considered an indication of future stock price performance. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



Cumulative Total Return Comparison

	1/31/2020 (Inception)	6/30/2020	12/31/2020	6/30/2021	12/31/2021
Arcutis Biotherapeutics, Inc.	$100.00	$138.72	$129.04	$125.18	$95.14
Nasdaq Composite Index	$100.00	$109.92	$140.84	$158.50	$172.02
Nasdaq Biotechnology Index	$100.00	$120.23	$133.14	$144.02	$133.45

Item 6. SELECTED FINANCIAL DATA

The following tables set forth our selected statements of operations and balance sheet data. The selected statements of operations data for the years ended December 31, 2021, 2020 and 2019, and the selected balance sheet data as of December 31, 2021, 2020, and 2019, are derived from our audited financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K, which financial statements have been audited by our independent registered public accounting firm. The following selected financial data below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in any future period. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,		
	2021	2020	2019
	(in thousands, except share and per share data)		
Statements of operations data:			
Operating expenses:			
Research and development	$ 145,558	$ 115,308	$ 36,522
General and administrative	60,971	21,337	6,610
Total operating expenses	$ 206,529	$ 136,645	$ 43,132
Loss from operations	(206,529)	(136,645)	(43,132)
Other income, net	173	967	1,136
Net loss	$ (206,356)	$ (135,678)	$ (41,996)
Net loss per share, basic and diluted[(1)]	$ (4.18)	$ (3.80)	$ (22.78)
Weighted-average shares used in computing net loss per share, basic and diluted[(1)]	49,405,575	35,668,152	1,843,213

(1) See Notes 2 and 12 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for a description of how we compute basic and diluted net loss per share and the weighted-average number of shares used in the computation of these per share amounts.

	December 31,		
	2021	2020	2019
		(in thousands)	
Balance sheet data:			
Cash, cash equivalents, restricted cash and marketable securities	$ 388,601	$ 285,983	$ 101,265
Working capital[(1)]	369,447	270,224	101,237
Total assets	408,152	298,269	107,012
Convertible preferred stock	—	—	166,491
Long-term debt, net	72,350	—	—
Accumulated deficit	(408,306)	(201,950)	(66,272)
Total stockholders' equity (deficit)	297,677	270,621	(65,029)

(1) We define working capital as current assets less current liabilities. See our financial statements and related notes for further details regarding our current assets and current liabilities.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our "Selected Financial Data" and our audited financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans, objectives, expectations, projections and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors identified below and those set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results and the timing of selected events could differ materially from the forward-looking statements contained in the following discussion and analysis. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a 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 drug development 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, demonstrating symptomatic improvement and favorable tolerability in this population. We have submitted a NDA to the FDA, and the FDA has set a PDUFA action date of July 29, 2022. Roflumilast cream is a once-daily topical formulation of roflumilast, a highly potent and selective PDE4 inhibitor. PDE4 is an established biological target in dermatology, with multiple PDE4 inhibitors approved by the FDA for the systematic treatment of 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 subjects showing continued symptomatic improvement and favorable tolerability over a treatment period of 52 to 64 weeks. In atopic dermatitis, we have initiated three pivotal Phase 3 clinical studies: INTEGUMENT-1 and -2 are enrolling subjects six years of age or older and INTEGUMENT-PED is enrolling subjects between the ages of two and five years. We expect to provide topline data from each of INTEGUMENT-1 and -2 by the end of 2022. We intend to submit an sNDA for topical roflumilast cream for the treatment of atopic dermatitis patients aged six years or older in 2023 based on the results of INTEGUMENT-1 and -2. We expect to provide topline data from INTEGUMENT-PED in 2023 and submit a subsequent sNDA for the younger age cohort following the potential initial atopic dermatitis approval in patients aged six years or older.

We are also developing a topical foam formulation of roflumilast, and have successfully completed Phase 2 clinical trials in both seborrheic dermatitis and scalp and body psoriasis. In seborrheic dermatitis, we have initiated a single pivotal Phase 3 clinical trial, with topline data anticipated in mid-year 2022. We also initiated a single pivotal Phase 3 clinical trial in scalp and body psoriasis indications, with topline data anticipated in the second half of 2022. If these pivotal Phase 3 trials for roflumilast foam are positive, we expect the data to be sufficient basis for an NDA submission to the FDA for each indication.

Beyond topical roflumilast, we are developing ARQ-252, a potent and highly selective topical JAK1 inhibitor. In May 2021, we announced that the Phase 2 study of ARQ-252 in chronic hand eczema did not meet its primary endpoint with further analyses of the study pointing to inadequate local drug delivery to the skin. Given these analyses, we also elected to terminate the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment in vitiligo, as we began reformulation efforts to develop an enhanced formulation of ARQ-252 that delivers more active drug to targets in the skin. Additionally, we have formulation and nonclinical efforts continuing for ARQ-255, an alternative deep-penetrating topical formulation of ARQ-252 designed to reach deeper into the skin and hair follicle in order to potentially treat alopecia areata.The ARQ-255 formulation is separate and distinct from ARQ-252, and thus there are no implications to ARQ-255 from ARQ-252.

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 equity and debt offerings. Prior to our IPO, we received $162.5 million in net cash proceeds from private placements of our convertible preferred stock. On February 4, 2020, we received $167.2 million in net proceeds in connection with our IPO. On October 6, 2020, we closed a public offering and a concurrent private placement of our common stock and received an aggregate of $128.4 million in net proceeds. Also, on February 5, 2021, we closed a public offering of our common stock and received an aggregate of $207.5 million in net proceeds. On December 22, 2021, we entered into a loan and security agreement, or the Loan Agreement, with SLR Investment Corp. (SLR) and the lenders party thereto for an aggregate principal amount of $225.0 million, of which $75.0 million has been funded and is outstanding, resulting in net proceeds of $72.4 million. See Note 1 to the financial statements for additional information.

We have incurred net losses in each year since inception, including net losses of $206.4 million, $135.7 million and $42.0 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $408.3 million and cash, cash equivalents, restricted cash and marketable securities of $388.6 million. As of December 31, 2021, we had $75.0 million outstanding under the Loan Agreement and an aggregate of up to $150.0 million in additional funding under the Loan Agreement that may become available subject to the satisfaction of specified conditions.

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 nonclinical 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, combined with committed funding under the Loan Agreement, will be sufficient to fund our operations into 2024.

We rely on third parties in the conduct of our nonclinical 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 nonclinical 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. We believe that the rapid spread of the Omicron variant in late 2021 and early 2022 has likely had a minor impact on the enrollment of our clinical trials. Because of this likely impact, along with the inherent challenges of enrolling young children in clinical trials, we have updated our expectation for providing topline data for the INTEGUMENT-PED trial, in atopic dermatitis subjects between two and five years of age, to 2023. 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, including our commercialization activities.

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

In alignment with public health guidance designed to slow the spread of COVID-19, we implemented a remote work plan for all employees as of mid-March 2020. We may need to undertake additional actions that could impact our operations as required by applicable laws or regulations, or which we determine to be in the best interests of our employees.

License Agreements

AstraZeneca License Agreement

In July 2018, we entered into 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 convertible preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product. We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specific regulatory approval milestones with respect to the AZ-Licensed Products, which includes $7.5 million upon FDA approval of our first product, and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. See Note 6 to the 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 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 nonclinical 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, nonclinical 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 allocable on a program specific basis.

We expect to continue to incur substantial research and development expenses in the future as we develop our product candidates. In particular, we expect to incur substantial research and development expenses for the Phase 3 trials of roflumilast cream for atopic dermatitis, the Phase 3 trials of roflumilast foam for seborrheic dermatitis and scalp and body psoriasis, ARQ-252 for chronic hand eczema and vitiligo, and ARQ-255 for alopecia areata.

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

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing, or costs required to complete the remaining development of roflumilast cream, roflumilast foam, ARQ-252, and ARQ-255, or any future product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See “Risk Factors” for a discussion of the risks and uncertainties associated with the development of our product candidates.

General and Administrative Expenses

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

Other Income, Net

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

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

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

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands)			
Operating expenses:				
Research and development	$ 145,558	$ 115,308	$ 30,250	26 %
General and administrative	60,971	21,337	39,634	186 %
Total operating expenses	$ 206,529	$ 136,645	$ 69,884	51 %
Loss from operations	(206,529)	(136,645)	(69,884)	51 %
Other income, net	173	967	(794)	(82)%
Net loss	$ (206,356)	$ (135,678)	$ (70,678)	52 %

Research and Development Expenses

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 89,196	$ 80,971	$ 8,225	10 %
Topical JAK inhibitor program	11,683	14,691	(3,008)	(20)%
Other early stage programs	548	250	298	119 %
Indirect costs:				
Compensation and personnel-related	28,729	13,747	14,982	109 %
Other	15,402	5,649	9,753	173 %
Total research and development expense	$ 145,558	$ 115,308	$ 30,250	26 %

Research and development expenses increased by $30.3 million, or 26%, for the year ended December 31, 2021 compared to the year ended December 31, 2020. The increase was primarily due to an increase in compensation and personnel-related costs of $15.0 million, an increase in other indirect costs of $9.8 million, and an increase in direct costs related to the topical roflumilast program of $8.2 million. These increases were partially offset by a decrease in direct costs related to the topical JAK inhibitor program (ARQ-252 and ARQ-255) of $3.0 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount to manage our growing clinical programs. The increase in other indirect costs was primarily due to an increase in medical affairs spending and consulting activity. The increase in topical roflumilast program costs was primarily due to increased manufacturing costs partially offset by a decrease in clinical trial costs. Clinical trial costs declined due to the completion of Phase 3 studies of roflumilast cream in plaque psoriasis, partially offset by the initiation of Phase 3 studies of roflumilast cream in atopic dermatitis and Phase 3 studies of roflumilast foam in seborrheic dermatitis and scalp psoriasis. The decrease in topical JAK inhibitor program costs was primarily due to the completion of our Phase 2 study of ARQ-252 in chronic hand eczema.

General and Administrative Expenses

General and administrative expenses increased by $39.6 million, or 186%, for the year ended December 31, 2021 compared to the year ended December 31, 2020. The increase was primarily due to an increase in compensation and personnel related expenses of $25.3 million, and an increase in professional services of $13.1 million. The increase in compensation and personnel related expenses, which includes stock-based compensation, was primarily due to an increase in headcount as we prepare for commercialization. The increase in professional services was due to an increase in sales and marketing expenses and consulting activity.

Other Income, Net

Other income, net decreased by $0.8 million, or 82%, for the year ended December 31, 2021 compared to the year ended December 31, 2020. The decrease was primarily due to a lower yield on our investment portfolio.

Comparison of the Years Ended December 31, 2020 and 2019

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

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Operating expenses:				
Research and development	$ 115,308	$ 36,522	$ 78,786	216 %
General and administrative	21,337	6,610	14,727	223 %
Total operating expenses	$ 136,645	$ 43,132	$ 93,513	217 %
Loss from operations	(136,645)	(43,132)	(93,513)	217 %
Other income, net	967	1,136	(169)	(15)%
Net loss	$ (135,678)	$ (41,996)	$ (93,682)	223 %

Research and Development Expenses

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 80,971	$ 26,677	$ 54,294	204 %
Topical JAK inhibitor program	14,691	3,379	11,312	335 %
Other early stage programs	250	22	228	1036 %
Indirect costs:				
Compensation and personnel-related	13,747	4,590	9,157	199 %
Other	5,649	1,854	3,795	205 %
Total research and development expense	$ 115,308	$ 36,522	$ 78,786	216 %

Research and development expenses increased by $78.8 million, or 216%, for the year ended December 31, 2020 compared to the year ended December 31, 2019. The increase was due to an increase in direct costs related to the topical roflumilast program of $54.3 million, an increase in direct costs related to the topical JAK inhibitor program of $11.3 million, an increase in compensation and personnel-related expenses of $9.2 million, and an increase of $3.8 million in other indirect costs which includes regulatory, research and clinical consulting costs. The increase in topical roflumilast program costs was primarily due to new and ongoing studies, including Phase 3 studies of roflumilast cream for plaque psoriasis, Phase 2 studies of roflumilast foam in scalp psoriasis and seborrheic dermatitis, as well as an increase in manufacturing costs. The increase in compensation and personnel-related expenses, which includes stock compensation, was primarily due to an increase in headcount.

General and Administrative Expenses

General and administrative expenses increased by $14.7 million, or 223%, for the year ended December 31, 2020 compared to the year ended December 31, 2019. The increase was primarily due to an increase in compensation and personnel-related expenses of $7.6 million, an increase in professional services of $3.8 million, and an increase in insurance costs of $2.6 million. The increase in compensation and personnel-related expenses, which includes stock compensation, was primarily due to an increase in headcount. The increases in professional services and insurance costs were mainly due to overall Company growth and the costs associated with being a public company.

Other Income, Net

Other income, net decreased by $0.2 million, or 15%, for the year ended December 31, 2020 compared to the year ended December 31, 2019. The decrease was primarily due to a lower yield on our investment portfolio, partially offset by higher balances.

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 nonclinical and clinical trials and providing general and administrative support for these operations. As of December 31, 2021 and 2020, we had cash, cash equivalents, restricted cash, and marketable securities of $388.6 million and $286.0 million, respectively, and an accumulated deficit of $408.3 million and $202.0 million, respectively. As of December 31, 2021, we had $75.0 million outstanding under our loan and security agreement, or the Loan Agreement, with SLR Investment Corp., or SLR, and the lenders party thereto.

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 equity offerings in October 2020 and February 2021. During the year ended December 31, 2021, we expanded our financing sources to include our ATM program and our Loan Agreement. On May 6, 2021, we entered into a Sales Agreement with Cowen, to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $100.0 million through an ATM equity offering program. During the year ended December 31, 2021, we did not issue or sell any shares of our common stock through our ATM program. On December 22, 2021 we entered into a Loan Agreement with SLR and the lenders party thereto. Pursuant to the Loan Agreement, the lenders agreed to extend term loans to the us in an aggregate principal amount of up to $225.0 million, comprised of four tranches that become available subject to the satisfaction of specified conditions. We received gross proceeds of $75.0 million from the first tranche on December 22, 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.

Funding Requirements

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $408.3 million and $202.0 million as of December 31, 2021 and 2020, respectively. We had cash, cash equivalents, and marketable securities of $387.1 million and $284.4 million as of December 31, 2021 and 2020, respectively. As of December 31, 2021, we had $75.0 million outstanding under our Loan Agreement and an aggregate of up to $150.0 million in additional funding that may become available subject to the satisfaction of specified conditions. Based on our current planned operations, we expect that our current cash, cash equivalents, and marketable securities, combined with committed funding under the Loan Agreement, will be sufficient to fund our operations into 2024. 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, accessing or incurring additional 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 nonclinical 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 nonclinical efforts for ARQ-255 in alopecia areata;
- suspensions or delays in the enrollment or changes to the number of subjects 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.

Indebtedness

On December 22, 2021 we entered into a Loan Agreement with SLR and the lenders party thereto. Pursuant to the Loan Agreement, the lenders agreed to extend term loans to the us in an aggregate principal amount of up to $225.0 million, comprised of: (i) a tranche A term loan of $75.0 million, (ii) a tranche B-1 term loan of $50.0 million, (iii) a tranche B-2 term loan of up to $75.0 million, available in minimum increments of $15.0 million, and (iv) a tranche C term loan of up to $25.0 million. We refer to the tranche A, tranche B and tranche C term loans together as our Term Loans. As security for the obligations under the Loan Agreement, we granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of our assets, including our intellectual property, subject to certain exceptions.

The tranche A term loan was funded on December 22, 2021. Each tranche B term loan is available following delivery to SLR of satisfactory evidence that we have received FDA approval of roflumilast cream for an indication relating to the treatment of patients with plaque psoriasis, which we refer to as the FDA Approval. The tranche B-1 term loan will remain available for funding until the earlier of (i) 15 days after we have received FDA Approval and (ii) June 30, 2023. The tranche B-2 term loan will remain available for funding until June 30, 2023. The tranche C term loan is available following the achievement of a net product revenue milestone of $110.0 million, calculated on a trailing six month basis. The tranche C term loan will remain available for funding until September 30, 2024.

Principal amounts outstanding under the Term Loans will accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. The applicable rate is a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. On December 31, 2021, the rate was 7.55%.

Commencing on February 1, 2022, interest payments are payable monthly following the funding of any Term Loan. Any principal amounts outstanding under the Term Loans, if not repaid sooner, are due and payable on January 1, 2027, or the Maturity Date. We may voluntarily prepay principal amounts outstanding under the Term Loans in minimum increments of $5.0 million, subject to a prepayment premium of (i) 3.0% of the principal amount of such Term Loan so prepaid prior to December 22, 2022, (ii) 2.0% of the principal amount of such Term Loan so prepaid after December 22, 2022 and prior to December 22, 2023, or (iii) 1.0% of the principal amount of such Term Loan so prepaid after December 22, 2023 and prior to December 22, 2025.

If the Term Loans are accelerated due to, among others, the occurrence of a bankruptcy or insolvency event, we are required to make mandatory prepayments of (i) all principal amounts outstanding under the Term Loans, plus accrued and unpaid interest thereon through the prepayment date, (ii) any fees applicable by reason of such prepayment, (iii) the prepayment premiums set forth in the paragraph above, plus (iv) all other obligations that are due and payable, including expenses and interest at the Default Rate (as defined below) with respect to any past due amounts.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. We have also agreed to a financial covenant whereby, beginning with the month ending December 31, 2023, we must generate net product revenue in excess of specified amounts for applicable measuring periods; provided, however, that such financial covenant shall not apply if our average market capitalization over the trailing five day period prior to the last day of any measurement month is equal to or in excess of $400.0 million. We were in compliance with all covenants under the Loan Agreement as of December 31, 2021.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the Term Loans. Under the Loan Agreement, an event of default will occur if, among other things, we fail to make payments under the Loan Agreement, we breach any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, the lenders determine that a material adverse change has occurred, or we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement.

In connection with the Loan Agreement, we paid a closing fee of $1.0 million on December 22, 2021, and we are further obligated to pay (i) a final fee equal to 6.95% of the aggregate original principal amount of the Term Loans funded upon the earliest to occur of the Maturity Date, the acceleration of any Term Loan and the prepayment, refinancing, substitution or replacement of any Term Loan and (ii) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the Loan Agreement, we entered into an Exit Fee Agreement, whereby we agreed to pay an exit fee in the amount 3.0% of each Term Loan funded upon (i) any change of control transaction or (ii) a revenue milestone, calculated on a trailing six month basis. Notwithstanding the prepayment or termination of the Term Loan, the exit fee will expire 10 years from the date of the Loan Agreement.

Cash Flows

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

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Cash used in operating activities	$ (174,627)	$ (113,033)	$ (42,836)
Cash used in investing activities	(75,953)	(181,824)	(26,325)
Cash provided by financing activities	281,947	298,145	93,103
Net increase in cash, cash equivalents and restricted cash	$ 31,367	$ 3,288	$ 23,942

Net Cash Used in Operating Activities

During the year ended December 31, 2021, net cash used in operating activities was $174.6 million, which consisted of a net loss of $206.4 million, partially offset by net non-cash charges of $28.1 million and a change in net operating assets and liabilities of $3.6 million. The net non-cash charges were primarily related to stock-based compensation expense of $23.9 million. The change in net operating assets and liabilities was primarily due to an increase of $10.7 million in accounts payable and accrued liabilities due to an increase in bonus and clinical accruals, partially offset by an increase of $7.3 million in prepaid expenses and other current assets.

During the year ended December 31, 2020, net cash used in operating activities was $113.0 million, which consisted of a net loss of $135.7 million, offset by a change in net operating assets and liabilities of $14.1 million and net non-cash charges of $8.5 million. The change in net operating assets and liabilities was primarily due to an increase of $17.6 million in accounts payable and accrued liabilities due to our operating expense growth and timing of payments. The net non-cash charges were primarily related to stock-based compensation expense of $7.9 million.

During the year ended December 31, 2019, net cash used in operating activities was $42.8 million, which consisted of a net loss of $42.0 million, a change in net operating assets and liabilities of $1.5 million, partially offset by net non-cash charges of $0.7 million. The change in net operating assets and liabilities was due to an increase of $3.3 million in prepaid expenses and other current assets for advances made for clinical trial costs, partially offset by an increase of $1.9 million in accounts payable and accrued liabilities due to our overall growth, increased research and development spending and timing of payments. The net non-cash charges were primarily related to stock-based compensation expense of $0.8 million, and depreciation and right-of-use asset amortization of $0.2 million, partially offset by net amortization/accretion on marketable securities of $0.4 million.

Net Cash Used in Investing Activities

During the year ended December 31, 2021, net cash used in investing activities was $76.0 million, which was comprised primarily of purchases of marketable securities of $292.5 million, partially offset by the proceeds from the maturities of marketable securities of $217.6 million.

During the year ended December 31, 2020, net cash used in investing activities was $181.8 million, which was comprised primarily of purchases of marketable securities of $279.1 million, partially offset by proceeds from the maturities of marketable securities of $97.6 million.

During the year ended December 31, 2019, net cash used in investing activities was $26.3 million, which was comprised of purchases of marketable securities of $60.8 million and property and equipment of $0.3 million, partially offset by proceeds from the maturities of marketable securities of $34.8 million.

Net Cash Provided by Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $281.9 million, which was comprised primarily of the net cash proceeds received from the follow-on financing in February 2021 of $207.5 million as well as from our debt financing in December 2021 of $72.4 million.

During the year ended December 31, 2020, net cash provided by financing activities was $298.1 million, which was comprised primarily of the net cash proceeds received from the IPO of $168.6 million and follow-on financing in October 2020 of $128.4 million.

During the year ended December 31, 2019, net cash provided by financing activities was $93.1 million, which was comprised of the net proceeds received from the issuance of Series C convertible preferred stock of $94.2 million as well as the proceeds from the exercise of stock options of $0.3 million, offset by deferred financing costs of $1.4 million paid in connection with the IPO.

Contractual Obligations and Contingent Liabilities

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

Facility Operating Lease

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

The lease is subject to fixed rate escalation increases with an initial base rent of $76,000 per month and includes rent free periods aggregating approximately one year. The amended lease agreement required that we deliver a letter of credit to the landlord of $1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, in November 2020, we entered into a letter of credit for $1.5 million, which is secured with a restricted cash account in the same amount. The total commitment under the operating lease agreement is $6.6 million, including $0.8 million for the year 2022, $1.0 million for each of the years 2023 through 2027, and $0.6 million for the year 2028. See Note 7 to the financial statements for additional information.

Manufacturing Agreements

We have entered into manufacturing supply agreements for the commercial supply of roflumilast cream that include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $8.2 million for 2022 and $0.6 million per year for 2023, 2024 and 2025. This amount does not represent all of our anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

Long-Term Debt Obligations

As of December 31, 2021, we had $75.0 million outstanding under our Loan Agreement and an aggregate of up to $150.0 million in additional funding under the Loan Agreement that may become available subject to the satisfaction of specified conditions. The total commitment under the Loan Agreement is $108.9 million, including $5.7 million for each of the years 2022 through 2026, and $80.2 million for 2027. These amounts do not represent or include any future draw downs, but instead represent only the contractually obligated minimum payments of interest, principal, and loan fees related to the funding of the $75.0 million tranche A term loan on December 22, 2021.

License Agreements

The terms of certain of our license agreements require us to pay potential future milestone payments based on product development and commercial success. The amount and timing of such obligations are unknown or uncertain. These potential obligations are further described in Note 6 to the financial statements.

Indemnification

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

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Use of Estimates

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

While our significant accounting policies are more fully described in the notes to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

Nonclinical and Clinical Accruals and Costs

We record accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of nonclinical studies, clinical studies, clinical trials and contract manufacturing activities. These costs are a significant component of our research and development expenses. Research and development costs are expensed as incurred unless there is an alternative future use in other research and development projects. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with third-party service providers under the service agreements. As it relates to clinical trials, the financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized. Additionally, if expectations change such that we do not expect goods to be delivered or services to be rendered, such prepayments are charged to expense. Our objective is to reflect the appropriate expense in our financial statements by matching those expenses with the period in which the services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial utilizing financial models taking into consideration discussions with applicable personnel and outside service providers. In this manner, our clinical trial accrual is dependent in part upon the timely and accurate reporting of progress and efforts incurred from CROs, contract manufacturers and other third-party vendors. Although we expect our estimates to be materially consistent with actual amounts incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. We make significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust our accrued liabilities. We have not experienced any material differences between accrued costs as of December 31, 2021 and 2020 and actual costs incurred.

Stock-Based Compensation

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

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

Fair value of common stock—see the subsection titled "Common Stock Valuation" below.

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

Expected Volatility—Since we do not yet have sufficient trading history for our common stock to use it solely for our historical volatility, the expected volatility was estimated based a combination of our 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. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our stock price becomes available.

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

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

See Note 10 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

We recorded stock-based compensation expense of $23.9 million, $7.9 million, and $0.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, there was $54.0 million of unrecognized compensation expense related to unvested options, which are expected to be recognized over a weighted-average period of approximately 3.0 years. As of December 31, 2021, there was $7.1 million of unrecognized compensation expense related to restricted stock, which are expected to be recognized over a weighted-average period of approximately 3.0 years. We expect to continue to grant stock options, restricted stock, and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

Common Stock Valuation

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

- contemporaneous valuations of our shares of common stock;
- the prices of each of our series of preferred stock sold by us to outside investors in arm's length transactions, and the rights, preferences and privileges of each of these series of preferred stock relative to our common stock;
- our results of operations, financial position and the status of our research and development efforts;
- the composition of our management team and board of directors;
- the material risks related to our business;
- the market performance of publicly traded companies in the life sciences and biotechnology sectors;

- the likelihood of achieving a liquidity event for the holders of our shares of common stock, such as a sale of the company or an IPO, given prevailing market conditions;
- the lack of marketability of our common stock; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

If we had made different assumptions than those described below, the fair value of the underlying common stock and amount of our stock-based compensation expense, net loss and net loss per share amounts would have differed. Following the closing of our IPO, the fair value per share of our common stock for purposes of determining stock-based compensation will be the closing price of our common stock as reported on the applicable grant date.

Historically, prior to our IPO, fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. Our board of directors considered, among other things, valuations of our common stock which were prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the AICPA Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

In 2019, we reassessed the determination of the fair value of the common shares underlying the grants made prior to August 2018 in connection with a valuation of the convertible preferred stock liability. This analysis revised our implied equity value, which was then allocated to each equity class using an option pricing method and the implied value of common stock was then reduced by a discount for lack of marketability. As a result of this reassessment, we determined that fair value of common stock increased to $0.46, $1.12 and $1.18 per share as of April 2017, December 2017 and March 2018, respectively. The increase to both recognized and unrecognized share-based compensation expense due to these higher share prices was approximately $0.1 million and $0.4 million, respectively, as of December 31, 2018.

Income Taxes

As of December 31, 2021, we had net deferred tax assets of $90.4 million. The deferred tax assets have been offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of NOL, tax carryforwards. As of December 31, 2021, we had federal, California and other state NOL carryforwards of $361.3 million, $360.1 million and $5.3 million, respectively, available to potentially offset future taxable income. As of December 31, 2021, we also had federal and California research and development tax credit carryforwards of approximately $10.8 million and $2.4 million, respectively, available to potentially offset future federal income taxes. The federal research and development tax carryforwards, if not utilized, will expire beginning in 2036. The California research and development tax credit carryforwards are available indefinitely. Federal and California tax law impose significant restrictions on the utilization of NOL carryforwards in the event of a change in ownership, as defined by Internal Revenue Code Section 382 and 383. We have not completed a formal study to determine any limitations on our tax attributes due to changes in ownership and may have limitations on the utilization of NOL carryforwards, credit carryforwards, or other tax attributes due to ownership changes.

Recent Accounting Pronouncements

See Note 2 to our financial statements.

Item 7A. 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 December 31, 2021, we had cash and cash equivalents of $96.4 million, restricted cash of $1.5 million and marketable securities of $290.6 million, which consist of bank deposits, money market funds, commercial paper, government securities, and corporate debt securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that this 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.

In addition, amounts outstanding under our Loan Agreement bear interest at a floating rate equal a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. As a result, we are exposed to risks related to our indebtedness from changes in interest rates. We do not believe that a hypothetical 100 basis point increase or decrease in the applicable interest rate would have had a significant impact on our interest expense for the year ended December 31, 2021.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements, together with the independent registered public accounting firm report thereon, are set forth in Part IV Item 15, “Exhibits, Financial Statement Schedules” of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2021, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such required information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based our assessment on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2021. The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by an independent registered public accounting firm, as stated in their report included in Part IV Item 15, “Exhibits, Financial Statement Schedules” of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting during the year ended December 31, 2021 covered by this Annual Report on Form 10-K 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

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Arcutis Biotherapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Arcutis Biotherapeutics, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Arcutis Biotherapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the balance sheets of the Company as of December 31, 2021 and 2020, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 22, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California

February 22, 2022

Item 9B. OTHER INFORMATION

None.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

Part III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Part IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Financial Statement Schedules.

The following financial statements are included herein:

(b) Exhibits.

Exhibit Number	Description of Document	Incorporated by Reference Form	Date	Number	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation.	S-1/A	1/21/20	3.2	
3.2	Restated Bylaws.	S-1/A	1/21/20	3.4	
4.1	Form of Common Stock Certificate.	S-1/A	1/21/20	4.1	
4.2†	Amended and Restated Investors' Rights Agreement, dated October 8, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	1/21/20	4.2	
4.3	Description of Arcutis Biotherapeutics' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	3/19/20	4.3	
10.1#	Form of Indemnity Agreement.	S-1	1/6/20	10.1	
10.2#	2017 Stock Incentive Plan and forms of award agreements.	S-1	1/6/20	10.2	
10.3#	2020 Stock Incentive Plan and forms of award agreements.	S-1/A	1/21/20	10.3	
10.4#	2020 Employee Stock Purchase Plan and forms of award agreements.	S-1/A	1/21/20	10.4	
10.5#	2022 Employment Inducement Incentive Plan and forms of award agreements.				*
10.6#	Offer Letter, dated January 9, 2020, by and between the Registrant and Todd Franklin Watanabe.	S-1/A	1/21/20	10.5	
10.7#	Offer Letter, dated January 9, 2020, by and between the Registrant and David W. Osborne.	S-1/A	1/21/20	10.6	
10.8#	Offer Letter, dated January 9, 2020, by and between the Registrant and Howard G. Welgus, M.D.	S-1/A	1/21/20	10.7	
10.9#	Offer Letter, dated January 9, 2020, by and between the Registrant and John W. Smither.	S-1/A	1/21/20	10.8	
10.10#	Offer Letter, dated January 9, 2020, by and between the Registrant and Kenneth A. Lock.	S-1/A	1/21/20	10.9	
10.11#	Offer Letter, dated January 9, 2020, by and between the Registrant and Patricia A. Turney.	S-1/A	1/21/20	10.10	
10.12#	Consulting Agreement, dated August 16, 2016, by and between Bhaskar Chaudhuri and the Registrant.	S-1	1/6/20	10.11	
10.13†^	License Agreement, dated July 23, 2018, by and between AstraZeneca AB and the Registrant.	S-1	1/6/20	10.12	
10.14†^	Exclusive Option and License Agreement, dated January 4, 2018, by and between Jiangsu Hengrui Medicine Co., Ltd. and the Registrant.	S-1	1/6/20	10.13	
10.15†^	Collaboration Agreement, dated June 28, 2019, by and between Hawkeye Therapeutics, Inc. and the Registrant.	S-1	1/6/20	10.14	
10.16#	Transition and Amendment Agreement, dated December 13, 2019 by and between Bhaskar Chaudhuri and the Registrant.	S-1	1/6/20	10.15	
10.17	Option Notice and Amendment No. 2 to Exclusive Option and License Agreement, dated December 5, 2019, by and between Jiangsu Hengrui Medicine Co., Ltd. and the Registrant.	S-1	1/6/20	10.16	
10.18#	Severance & Change in Control Agreement, by and between the Registrant and Todd Franklin Watanabe.	S-1/A	1/21/20	10.17	
10.19#	Severance & Change in Control Agreement, by and between the Registrant and David W. Osborne.	S-1/A	1/21/20	10.18	
10.20#	Severance & Change in Control Agreement, by and between the Registrant and Howard G. Welgus, M.D.	S-1/A	1/21/20	10.19	
10.21#	Severance & Change in Control Agreement, by and between the Registrant and John W. Smither.	S-1/A	1/21/20	10.20	

10.22#	Severance & Change in Control Agreement, by and between the Registrant and Kenneth A. Lock.	S-1/A	1/21/20	10.21	
10.23#	Severance & Change in Control Agreement, by and between the Registrant and Patricia A. Turney.	S-1/A	1/21/20	10.22	
10.24#	Offer Letter, dated December 18, 2020, by and between the Registrant and Matthew R. Moore.	10-K	2/16/21	10.23	
10.25#	Severance & Change in Control Agreement, by and between the Registrant and Matthew R. Moore.	10-K	2/16/21	10.24	
10.26†^	Supply Agreement, dated November 24, 2020, by and between Registrant and Interquim, S.A.	10-K	2/16/21	10.25	
10.27†^	Exclusive Distribution Agreement, dated February 8, 2021, by and between the Registrant and Cardinal Health 105, Inc.	10-Q	5/6/21	10.1	
10.28#	Severance & Change in Control Agreement, by and between the Registrant and Scott L. Burrows.	10-Q	5/6/21	10.2	
10.29	Sales Agreement, dated May 6, 2021, by and between the Registrant and Cowen and Company, LLC.	10-Q	5/6/21	10.3	
10.30†	Supply and Manufacturing Agreement, dated September 15, 2021, between DPT Laboratories, Ltd. and the Registrant.	10-Q	11/4/21	10.1	
10.31#	Offer Letter, dated December 13, 2021, by and between the Registrant and Mas Matsuda.				*
10.32#	Severance & Change in Control Agreement, by and between the Registrant and Mas Matsuda.				*
10.33^	Loan and Security Agreement, dated December 22, 2021, by and among the Registrant, SLR Investment Corp. and the lenders party thereto.				*
23.1	Consent of Independent Registered Public Accounting Firm.				*
24.1	Power of Attorney (included in the signature page to this Annual Report on Form 10-K).				*
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.				*
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.				*
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.				**
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.				*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				*

104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	*

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* Filed herewith.
** Furnished herewith.
† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.
^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.
# Indicates management contract or compensatory plan.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Arcutis Biotherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Arcutis Biotherapeutics, Inc. (the Company) as of December 31, 2021 and 2020, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 22, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Clinical Trial Costs

Description of the Matter

As of December 31, 2021, the Company recorded $13.2 million for accrued clinical trial costs. As described in Note 2 to the financial statements, the Company records accrued liabilities for estimated costs of clinical trial research and development activities conducted by third-party clinical research organizations (CROs). The Company accrues for these costs based on factors such as patient enrollment, estimates of the work completed as patients progress through the trials, and the related costs for the research activities in accordance with terms established with its third-party service providers under the respective service agreements.

Auditing the Company's accounting for accrued clinical trial costs was challenging because calculating the liability for clinical trial activity includes determining the progress or stage of completion of the activities within each clinical trial based on internal and external information, and involves a high volume of data.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the Company's process for estimating accrued clinical trial costs, including controls over management's measurement of clinical trial progress and the related estimates of costs incurred. We also tested controls over management's review of the completeness and accuracy of data used in determining the accruals.

To test the adequacy of the Company's accrued clinical trial costs, we performed audit procedures that included, among others, inspecting correspondence between internal clinical trial study managers and external clinical trial service providers for selected clinical trials and performing corroborative inquiries of accounting personnel and internal clinical project managers to validate the progress of clinical trial activities. To assess the appropriate measurement of accrued clinical trial costs, we reviewed significant agreements, and associated amendments and change orders, obtained external confirmation of key study dates and patient enrollment status directly with the CROs, selected a sample of transactions to inspect invoices, and vouched payments to bank statements. Additionally, we reviewed payments made subsequent to year-end to evaluate the completeness of the accrued clinical trial costs.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Los Angeles, California

February 22, 2022

ARCUTIS BIOTHERAPEUTICS, INC.

Balance Sheets

(In thousands, except share and par value)

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 96,449	$ 65,082
Restricted cash	1,542	1,542
Marketable securities	290,610	219,359
Prepaid expenses and other current assets	14,172	6,843
Total current assets	402,773	292,826
Property and equipment, net	2,261	2,016
Operating lease right-of-use asset	3,040	3,349
Other assets	78	78
Total assets	$ 408,152	$ 298,269
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,353	$ 7,140
Accrued liabilities	25,540	15,462
Operating lease liability	433	—
Total current liabilities	33,326	22,602
Operating lease liability, noncurrent	4,774	4,964
Long-term debt, net	72,350	—
Other long-term liabilities	25	82
Total liabilities	110,475	27,648
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2021 and December 31, 2020; no shares issued and outstanding at December 31, 2021 and December 31, 2020;	—	—
Common stock, $0.0001 par value; 300,000,000 and 300,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; 50,345,754 and 43,677,817 shares issued at December 31, 2021 and December 31, 2020, respectively; 50,255,614 and 43,338,438 shares outstanding at December 31, 2021 and December 31, 2020, respectively	5	4
Additional paid-in capital	706,233	472,569
Accumulated other comprehensive loss	(255)	(2)
Accumulated deficit	(408,306)	(201,950)
Total stockholders' equity	297,677	270,621
Total liabilities and stockholders' equity	$ 408,152	$ 298,269

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

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Year Ended December 31,		
	2021	2020	2019
Operating expenses:			
Research and development	$ 145,558	$ 115,308	$ 36,522
General and administrative	60,971	21,337	6,610
Total operating expenses	206,529	136,645	43,132
Loss from operations	(206,529)	(136,645)	(43,132)
Other income, net	173	967	1,136
Net loss	$ (206,356)	$ (135,678)	$ (41,996)
Other comprehensive loss:			
Unrealized loss on marketable securities	(253)	(1)	(1)
Comprehensive loss	$ (206,609)	$ (135,679)	$ (41,997)
Per share information:			
Net loss per share, basic and diluted	$ (4.18)	$ (3.80)	$ (22.78)
Weighted-average shares used in computing net loss per share, basic and diluted	49,405,575	35,668,152	1,843,213

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

ARCUTIS BIOTHERAPEUTICS, INC.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)

	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, 2018	16,262,425	$ 72,252	1,557,900	$ —	$ 289	$ —	$ (24,276)	$ (23,987)
Issuance of Series C convertible preferred stock, net of issuance costs of $262	8,122,963	94,239	—	—	—	—	—	—
Issuance of common stock upon the exercise of stock options	—	—	15,885	—	9	—	—	9
Issuance of common stock upon the vesting of restricted stock awards	—	—	13,245	—	8	—	—	8
Vesting of founder shares subject to repurchase	—	—	275,726	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	258,097	—	114	—	—	114
Stock-based compensation expense	—	—	—	—	824	—	—	824
Unrealized loss on marketable securities	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(41,996)	(41,996)
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 for public offering, net of issuance costs of $6,640	—	—	4,000,000	—	93,360	—	—	93,360
Issuance of shares of common stock for private placement	—	—	1,400,000	—	35,000	—	—	35,000
Issuance of common stock upon the exercise of stock options	—	—	140,226	—	430	—	—	430
Vesting of founder shares subject to repurchase	—	—	137,863	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	338,670	1	246	—	—	247
Shares issued pursuant to the employee stock purchase plan	—	—	34,188	—	617	—	—	617
Stock-based compensation expense	—	—	—	—	7,943	—	—	7,943
Unrealized loss on marketable securities	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(135,678)	(135,678)
Balance—December 31, 2020	—	$ —	43,338,438	$ 4	$ 472,569	$ (2)	$ (201,950)	$ 270,621
Issuance of shares of common stock for public offering, net of issuance costs of $603	—	—	6,325,000	1	207,489	—	—	207,490
Issuance of common stock upon the exercise of stock options	—	—	257,060	—	1,265	—	—	1,265
Issuance of common stock upon the vesting of restricted stock units	—	—	37,362	—	—	—	—	—
Lapse of repurchasing rights related to common stock issued pursuant to early exercises	—	—	249,239	—	176	—	—	176
Shares issued pursuant to the employee stock purchase plan	—	—	48,515	—	842	—	—	842
Stock-based compensation expense	—	—	—	—	23,892	—	—	23,892
Unrealized loss on marketable securities	—	—	—	—	—	(253)	—	(253)
Net loss	—	—	—	—	—	—	(206,356)	(206,356)
Balance—December 31, 2021	—	$ —	50,255,614	$ 5	$ 706,233	$ (255)	$ (408,306)	$ 297,677

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

ARCUTIS BIOTHERAPEUTICS, INC.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2021	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (206,356)	$ (135,678)	$ (41,996)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	454	122	68
Non-cash lease expense	309	333	127
Net amortization/accretion on marketable securities	3,454	72	(354)
Stock-based compensation	23,892	7,943	824
Loss on disposal of property and equipment	—	42	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(7,329)	(3,412)	(3,304)
Other assets	—	—	(47)
Accounts payable	245	5,674	(458)
Accrued liabilities	10,461	11,877	2,388
Operating lease liabilities	243	(6)	(84)
Net cash used in operating activities	(174,627)	(113,033)	(42,836)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of marketable securities	(292,508)	(279,103)	(60,830)
Proceeds from maturities of marketable securities	217,550	97,600	34,800
Purchases of property and equipment	(995)	(321)	(295)
Net cash used in investing activities	(75,953)	(181,824)	(26,325)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock upon exercise of stock options	1,265	526	265
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	—	94,239
Proceeds from initial public offering, net of issuance costs	—	168,642	—
Proceeds from issuance of common stock, net of issuance costs	207,490	128,360	—
Proceeds from issuance of common stock for ESPP purchase	842	617	—
Payment of financing costs	—	—	(1,401)
Proceeds from long-term debt, net	73,987	—	—
Debt issuance costs	(1,637)	—	—
Net cash provided by financing activities	281,947	298,145	93,103
Net increase in cash, cash equivalents and restricted cash	31,367	3,288	23,942
Cash, cash equivalents and restricted cash at beginning of period	66,624	63,336	39,394
Cash, cash equivalents and restricted cash at end of period	$ 97,991	$ 66,624	$ 63,336
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:			
Interest expense paid in cash	$ 142	$ —	$ —
Conversion of preferred stock to common stock and APIC	$ —	$ 166,491	$ —
Right-of-use asset obtained in exchange for lease liability	$ —	$ 3,617	$ 391
Reduction in right-of-use asset upon reassessment of lease term	$ —	$ 123	$ —
Deferred financing costs included in accounts payable and accrued liabilities	$ —	$ —	$ 346

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

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to 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 potential 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 drug development platform and deep dermatology expertise to develop differentiated products that have the potential to address the major shortcomings of existing therapies in its targeted indications. The Company believes this strategy uniquely positions it to rapidly advance its goal of bridging the treatment innovation gap in dermatology, while maximizing its probability of technical success.

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

Initial Public Offering and Follow-On Financings

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

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

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

At-the-Market (ATM) Offerings

On May 6, 2021, the Company entered into a sales agreement (Sales Agreement) with Cowen and Company, LLC (Cowen), under which the Company may from time to time issue and sell shares of its common stock through ATM offerings for an aggregate offering price of up to $100.0 million. Cowen will act as the Company's sales agent for the ATM program and is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold under the Sales Agreement. The Company has not yet issued or sold any shares of common stock through the ATM program.

Debt Financing

On December 22, 2021, the Company entered into a loan and security agreement (Loan Agreement) with SLR Investment Corp (SLR) and the lenders party thereto. The lenders agreed to extend term loans to the Company in an aggregate principal amount of up to $225.0 million, of which $75.0 million has been funded and is outstanding, and up to $150.0 million in additional funding may become available subject to the satisfaction of specified conditions. See Note 8.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $408.3 million and $202.0 million as of December 31, 2021 and 2020, respectively. The Company had cash, cash equivalents, restricted cash, and marketable securities of $388.6 million and $286.0 million as of December 31, 2021 and 2020, respectively. As of December 31, 2021, the Company had $75.0 million outstanding under the Loan Agreement and has an aggregate of up to $150.0 million in additional funding that may become available subject to the satisfaction of specified conditions. Prior to selling common stock in its IPO, the Company had historically financed its operations primarily through the sale of its convertible preferred stock. Management expects operating losses to continue for the foreseeable future.

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

Coronavirus Outbreak

In March 2020, the World Health Organization declared a pandemic related to the global novel coronavirus disease 2019 (COVID-19) outbreak. 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, as well as its planned commercial activities. The Company believes that the rapid spread of the Omicron variant in late 2021 and early 2022 has likely had a minor impact on the enrollment of our clinical trials. Because of this likely impact, along with the inherent challenges of enrolling young children in clinical trials, we have updated our expectation for providing topline data for the INTEGUMENT-PED trial, in atopic dermatitis subjects between two and five years of age, to 2023. 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 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 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.

JOBS Act Accounting Election

Effective December 31, 2021, the Company is no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act) because of an increase in its market capitalization. Prior to losing this status as an emerging growth company, the JOBS Act allowed the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements were made applicable to private companies, and the Company had elected to use this extended transition period. The Company can no longer take advantage of this extended transition period.

Segments

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

Cash and Cash Equivalents

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

Restricted Cash

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

Marketable Securities

Marketable securities consist of investment grade short to intermediate-term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase, including those that have maturity dates beyond one year from the balance sheet date, are classified as current assets on the balance sheets due to their highly liquid nature and availability for use in current operations.

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the 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, accrued liabilities, and long-term debt. The carrying amount of cash equivalents, accounts payable, and accrued liabilities approximate their fair values due to their short maturities. As the long-term debt is subject to variable interest rates that are based on market rates which regularly reset, the Company believes that the carrying value of the long-term debt approximates its fair value.

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.

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 years ended December 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.

Nonclinical 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 nonclinical studies, clinical trials, and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. For the years ended December 31, 2021, 2020 and 2019, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Convertible Preferred Stock

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

Research and Development

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

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

Stock-Based Compensation

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

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

Variable Interest Entities

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

Net Loss Per Share

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

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 financial statements.

3. Fair Value Measurements

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

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 95,145	$ —	$ —	$ 95,145
Commercial paper	—	119,413	—	119,413
Corporate debt securities	—	114,324	—	114,324
U.S. Treasury securities	58,177	—	—	58,177
Total assets	$ 153,322	$ 233,737	$ —	$ 387,059

	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.

Money market funds and U.S. Treasury securities are valued based on quoted market prices in active markets, with no valuation adjustment.

Commercial paper and corporate debt 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):

	December 31, 2021			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 95,145	$ —	$ —	$ 95,145
Corporate debt securities	1,304	—	—	1,304
Total cash and cash equivalents	$ 96,449	$ —	$ —	$ 96,449
Marketable securities:				
Commercial paper	$ 119,413	—	—	$ 119,413
Corporate debt securities	113,145		(125)	113,020
U.S. Treasury securities	58,307	—	(130)	58,177
Total marketable securities	$ 290,865	$ —	$ (255)	$ 290,610

(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 years ended December 31, 2021 and 2020 were not material. As of December 31, 2021 and 2020, unrealized losses on marketable securities were not material, and accordingly, no allowance for credit losses were recorded. As of December 31, 2021 and 2020, all securities have a maturity of 18 months or less and all securities with gross unrealized losses have been in a continuous loss position for less than one year.

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2021	2020
Prepaid clinical trial costs	$ 5,629	$ 4,865
Prepaid insurance	518	249
Tax credits	362	510
Other prepaid expenses and current assets	7,663	1,219
Total prepaid expenses and other current assets	$ 14,172	$ 6,843

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2021	2020
Clinical trial accruals	$ 13,217	$ 9,754
Accrued compensation	9,130	4,434
Accrued expenses and other current liabilities	3,193	1,274
Total accrued liabilities	$ 25,540	$ 15,462

5. Property and Equipment, net

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

	December 31,	
	2021	2020
Computer hardware	$ 775	$ 286
Furniture and fixtures	346	230
Software	104	—
Construction in process	—	298
Leasehold improvements	1,568	1,280
Property and equipment, gross	2,793	2,094
Less accumulated depreciation	(532)	(78)
Property and equipment, net	$ 2,261	$ 2,016

Depreciation expense was $454,000, $122,000, and $68,000 for the years ended December 31, 2021, 2020, and 2019 respectively. Leasehold improvements are depreciated over the term of the lease, which is the shorter of the improvements' expected useful lives and the lease term. All other fixed asset depreciation is recorded using the straight-line method over the estimated useful lives of the assets (two to five years).

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, which were both recorded in research and development expense. The Company subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of topical roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product, which was recorded in research and development expense. The Company has agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specified regulatory approval milestones with respect to the AZ-Licensed Products, which includes $7.5 million upon FDA approval of the Company's first product, and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products the Company commercializes under the AstraZeneca License Agreement, it will pay AstraZeneca a low to high single-digit percentage royalty rate on the Company’s, its affiliates’ and its sublicensees’ net sales of such AZ-Licensed Products, subject to specified reductions, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country.

There were no payments made or due in connection with AZ-Licensed Products for the years ended December 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.

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 years ended December 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 at the time of the purchase. In the event that Hawkeye issues shares of Series A convertible 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 convertible 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 and was amended in April 2020 in order to relocate to a new expanded space comprising 22,643 square feet.

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Notes to Financial Statements

The Company recognized the ROU asset and lease liability for the new space on May 1, 2020. The lease payment term for the new space began on December 30, 2020. 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.

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, which the Company fully utilized by incurring related costs. This amount, along with $320,000 of additional costs incurred for leasehold improvements beyond the allowance, were capitalized and included in property and equipment as of December 31, 2020. The amended lease agreement 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.

In association with commencement of this new lease, the Company recorded lease liabilities and ROU assets of $3.6 million on its balance sheet as of June 30, 2020. All leasehold improvements will be depreciated over the remaining term of the lease.

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

	Amounts
2022	$ 781
2023	964
2024	994
2025	1,025
2026	1,054
Thereafter	1,740
Total minimum lease payments	$ 6,558
Less: Amounts representing interest	(1,351)
Present value of future minimum lease payments	$ 5,207
Current portion operating lease liability	433
Operating lease liability, noncurrent	4,774
Total operating lease liability	$ 5,207

Straight-line rent expense recognized for operating leases was $686,000, $602,000, and $151,000 for the years ended December 31, 2021, 2020, and 2019, 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 years ended December 31, 2021, 2020, and 2019.

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

	December 31,		
	2021	2020	2019
Cash flows from operating activities			
Cash paid for amounts included in the measurement of lease liabilities	$ 114	$ 192	$ 141

The following summarizes additional information related to the operating lease:

	December 31, 2021
Weighted-average remaining lease term (in years)	6.6
Weighted-average discount rate	7.0 %

Manufacturing Agreements

The Company has entered into manufacturing supply agreements for the commercial supply of roflumilast cream which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $8.2 million for 2022 and $0.6 million per year for 2023, 2024 and 2025. This amount does not represent all of the Company's anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

Indemnification

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

8. Long-term debt

On December 22, 2021, the Company entered into a Loan Agreement with SLR and the lenders party thereto. The lenders agreed to extend term loans to the Company in an aggregate principal amount of up to $225.0 million, comprised of (i) a tranche A term loan of $75.0 million, (ii) a tranche B-1 term loan of $50.0 million, (iii) a tranche B-2 term loan of up to $75.0 million, available in minimum increments of $15.0 million, and (iv) a tranche C term loan of up to $25.0 million (Term Loans). As security for the obligations under the Loan Agreement, the Company granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of the Company's assets, including its intellectual property, subject to certain exceptions.

The tranche A term loan under the Loan Agreement was funded on December 22, 2021 in the amount of $75.0 million. Each tranche B term loan is available following delivery to SLR of satisfactory evidence that the Company has received FDA approval of roflumilast cream for an indication relating to the treatment of patients with plaque psoriasis (FDA Approval). The tranche B-1 term loan will remain available for funding until the earlier of (i) 15 days after the Company has received FDA Approval and (ii) June 30, 2023. The tranche B-2 term loan will remain available for funding until June 30, 2023. The tranche C term loan is available following the achievement of a net product revenue milestone of $110.0 million, calculated on a trailing six month basis. The tranche C term loan will remain available for funding until September 30, 2024.

Principal amounts outstanding under the Term Loans will accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. The applicable rate is a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. On December 31, 2021, the rate was 7.55%. The maturity date for each term loan is January 1, 2027.

Commencing on February 1, 2022, interest payments are payable monthly following the funding of any Term Loan. Any principal amounts outstanding under the Term Loans, if not repaid sooner, are due and payable on January 1, 202, or the Maturity Date. The Company may voluntarily prepay principal amounts outstanding under the Term Loans in minimum increments of $5.0 million, subject to a prepayment premium of (i) 3.0% of the principal amount of such Term Loan so prepaid prior to December 22, 2022, (ii) 2.0% of the principal amount of such Term Loan so prepaid after December 22, 2022 and prior to December 22, 2023, or (iii) 1.0% of the principal amount of such Term Loan so prepaid after December 22, 2023 and prior to December 22, 2025.

If the Term Loans are accelerated due to, among others, the occurrence of a bankruptcy or insolvency event, the Company is required to make mandatory prepayments of (i) all principal amounts outstanding under the Term Loans, plus accrued and unpaid interest thereon through the prepayment date, (ii) any fees applicable by reason of such prepayment, (iii) the prepayment premiums set forth in the paragraph above, plus (iv) all other obligations that are due and payable, including expenses and interest at the Default Rate (as defined below) with respect to any past due amounts.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on the Company’s ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. The Company has also agreed to a financial covenant whereby, beginning with the month ending December 31, 2023, the Company must generate net product revenue in excess of specified amounts for applicable measuring periods; provided, however, that such financial covenant shall not apply if the Company’s average market capitalization over the trailing five day period prior to the last day of any measurement month is equal to or in excess of $400.0 million. The Company was in compliance with all covenants under the Loan Agreement as of December 31, 2021.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the Term Loans. Under the Loan Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Loan Agreement, the Company breaches any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, the lenders determine that a material adverse change has occurred, or the Company or the Company's assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement. The prepayment upon default and other potential additional interest provisions under the Loan Agreement were determined to be a compound embedded derivative instrument to be bifurcated from the loan and accounted for as a separate liability for accounting purposes under the guidance in ASC 815, Derivatives and Hedging. At the inception of the Loan Agreement and through December 31, 2021, the fair value of the embedded derivative was determined to be immaterial and will be remeasured at fair value each reporting period with any future changes in fair value reported in earnings.

In connection with the Loan Agreement, the Company paid a closing fee of $1.0 million on December 22, 2021, and is further obligated to pay (i) a final fee equal to 6.95% of the aggregate original principal amount of the Term Loans funded upon the earliest to occur of the Maturity Date, the acceleration of any Term Loan and the prepayment, refinancing, substitution or replacement of any Term Loan and (ii) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the Loan Agreement, the Company entered into an Exit Fee Agreement, whereby the Company agreed to pay an exit fee in the amount 3.0% of each Term Loan funded upon (i) any change of control transaction or (ii) a revenue milestone, calculated on a trailing six month basis. Notwithstanding the prepayment or termination of the Term Loan, the exit fee will expire 10 years from the date of the Loan Agreement.

As of December 31, 2021, the carrying value of the Term Loans consists of $75.0 million principal outstanding less the debt issuance costs of approximately $2.7 million, including the closing fee. The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan. Interest expense is calculated using the effective interest method, and is inclusive of non-cash amortization of debt issuance costs. The final maturity payment of $5.2 million is recognized over the life of the term loan through interest expense. As of December 31, 2021 the amortization of the deferred final fee and debt issuance costs was not material. At December 31, 2021, the effective interest rate was 9.64%. Interest expense relating to the term loan for the year ended December 31, 2021 was $140,000. As of December 31, 2020 the Company had no outstanding long-term debt.

The following summarizes additional information related to our long-term debt (in thousands):

	December 31, 2021
Long-term debt, gross	$ 80,213
Deferred final fee	(5,213)
Debt issuance costs	(2,650)
Long-term debt, net	$ 72,350

9. 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 December 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:

	December 31,	
	2021	2020
Options issued and outstanding	5,757,957	3,655,945
Common stock awards available for grant under employee incentive plans	2,068,004	2,501,329
Restricted stock units outstanding	335,196	162,930
Total common stock reserved	8,161,157	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 December 31, 2021 and 2020.

10. 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 (RSU) 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 beginning in 2021 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, 2022 and 2021, the plan reserve increased by 2,013,830 and 1,747,112 shares, respectively. As of December 31, 2021, the Company had 1,362,929 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.

In December 2021, the Company's board of directors approved the 2022 Employment Inducement Incentive Plan (2022 Plan). The 2022 Plan has 1,250,000 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, RSU awards, and other stock-based awards. No awards have been made out of this plan as of December 31, 2021.

Stock Option Activity

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

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2020	3,655,945	12.09	8.78	59,274
Granted	2,706,171	27.65		
Exercised	(257,060)	4.88		
Forfeited	(288,858)	22.11		
Expired	(58,241)	28.19		
Balance—December 31, 2021	5,757,957	19.06	8.37	34,887
Exercisable—12/31/2021[(1)]	2,451,373	10.83	7.46	29,467

(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 December 31, 2021. As of December 31, 2020, prior to the Company's IPO in January 2020, the estimated fair value of the Company's common stock was determined by the board of directors.

The intrinsic value of options exercised for the year ended December 31, 2021 was $5.8 million.

The total grant-date fair value of the options vested during the year ended December 31, 2021 was $14.3 million. The weighted-average grant-date fair value of employee options granted during the year ended December 31, 2021 was $19.21.

Restricted Stock Unit Activity

The following table summarizes information regarding our RSUs:

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2020	162,930	$ 27.26
Granted	225,900	$ 30.51
Vested	(37,362)	$ 27.19
Forfeited	(16,272)	$ 31.23
Unvested Balance—December 31, 2021	335,196	$ 29.26

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 statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Research and development	$ 8,478	$ 3,503	$ 351
General and administrative	15,414	4,440	473
Total stock-based compensation expense	$ 23,892	$ 7,943	$ 824

As of December 31, 2021, there was $54.0 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 3.0 years. As of December 31, 2021, there was $7.1 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 3.0 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-based compensation expense during the period, which is included in general and administrative expenses.

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

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

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

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

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

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

The fair value of stock option awards granted was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	5.5 – 6.2	5.5 – 6.8	5.1 – 6.6
Expected volatility	80.6 – 85.2%	78.4 – 80.8%	68.6 – 72.5%
Risk-free interest rate	0.6 – 1.3%	0.3 – 1.4%	1.6 – 2.6%
Dividend yield	—%	—%	—%

Early Exercise of Employee Options

The terms of the 2017 and 2020 Plans permit certain option holders to exercise options before their options are vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement. The shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. 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 $82,000 and $258,000 as a liability from the early exercise in the accompanying balance sheets as of December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, there were $57,000 and $176,000 recorded in accrued liabilities, respectively, and $25,000 and $82,000 recorded in other long-term liabilities, respectively related to shares that were subject to repurchase.

Founder Awards

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

2020 Employee Stock Purchase Plan

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

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, 2022 and 2021, the ESPP reserve increased by 503,457 and 436,778 shares, respectively.

Stock-based compensation expense related to the ESPP was $442,000 and $346,000 for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, 82,703 shares of stock have been issued under the ESPP.

11. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2021, 2020 and 2019. The Company has incurred NOLs only in the United States since its inception. The Company has not reflected any benefit of such NOL carryforwards in the financial statements.

Reconciliation of income tax computed at federal statutory rates to the reported provision for income taxes is as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Tax provision at U.S. statutory rate	$ (43,336)	$ (28,493)	$ (8,819)
State income taxes, net of federal benefit	(13,394)	(9,213)	(2,786)
Research and development tax and other credits	(2,497)	(2,413)	(655)
Change in valuation allowance	44,675	30,708	9,598
Uncertain tax positions	12,562	8,801	2,604
Permanent differences	1,243	616	58
162(m) limitation	757	—	—
Other	(10)	(6)	—
Provision for income tax	$ —	$ —	$ —

ARCUTIS BIOTHERAPEUTICS, INC.
Notes to Financial Statements

Significant components of the Company's deferred income taxes were as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 76,202	$ 38,196
Intangibles	1,626	1,777
Research and development tax credits	5,832	3,370
Accruals and reserves	2,318	1,041
Right-of-use liability	1,336	1,274
Stock-based compensation	4,126	1,122
Gross deferred tax assets	$ 91,440	$ 46,780
Deferred tax liabilities:		
Property and equipment	$ (296)	$ (299)
Right-of-use asset	(780)	(859)
Gross deferred tax liabilities	$ (1,076)	$ (1,158)
Net deferred tax assets	$ 90,364	$ 45,622
Less valuation allowance	(90,364)	(45,622)
Total deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $44.7 million and $30.7 million during the years ended December 31, 2021 and 2020, respectively.

The Company has NOL carryforwards for federal, California and other state income tax purposes of approximately $361.3 million, $360.1 million and $5.3 million, respectively, as of December 31, 2021. Of the federal NOLs, $3.5 million originated before the 2018 tax year and will expire beginning in 2036. Under the Tax Cuts and Jobs Act of 2017, the remaining $357.8 million of NOLs generated after December 31, 2017 will be carried forward indefinitely. Of the $365.4 million in state net operating loss carryforwards $3.2 million can be carried forward indefinitely and the remaining start to expire in 2022.

On March 27, 2020, the CARES Act was signed into law in response to the economic challenges facing U.S. businesses. Under the CARES Act, the Internal Revenue Code was amended to allow for federal NOL carrybacks for five years to offset previous years income, or can be carryforward indefinitely to offset 100% of taxable income for the tax year 2020 and 80% of taxable income for tax years 2021 and thereafter. As of the date the financial statements were available to be issued, the state NOL carryforwards, if not utilized, will expire beginning in 2030.

As of December 31, 2021, the Company also had federal and California research and development tax credit carryforwards of $10.8 million and $2.4 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2037. The California research and development tax credit carryforwards are available indefinitely.

Federal and California tax laws impose significant restrictions on the utilization of NOL carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 and 383. The Company has not completed a formal study to determine the limitations on their tax attributes due to change in ownership and may have limitations on the utilization of NOL carryforwards, credit carryforwards, or other tax attributes due to ownership changes.

Uncertain Tax Benefits

No liability related to uncertain tax positions is recorded on the financial statements.

The following table summarizes the activity related to the unrecognized benefits (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Beginning balance	$ 20,274	$ 6,448	$ 2,241
Increases (decreases) related to tax positions taken during a prior year	(6)	5	4
Increases related to tax positions taken during the current year	18,674	13,821	4,203
Ending balance	$ 38,942	$ 20,274	$ 6,448

The reversal of the uncertain tax benefits would not affect the effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months.

Income tax returns are filed in the United States and California. The Company is not currently under audit by the Internal Revenue Service or similar state or local authorities. The years 2016 and forward remain open to examination by the domestic taxing jurisdictions to which the Company is subject. Due to NOL carryforwards, all years effectively remain open to income tax examination by the domestic taxing jurisdictions in which the Company files tax returns.

Included in unrecognized tax benefits of $38.9 million at December 31, 2021 was $31.9 million of tax benefits that, if recognized, would reduce our annual effective tax rate, subject to valuation allowance. The Company does not expect that there will be a significant change in the unrecognized tax benefits over the next 12 months.

The Company is subject to taxation in the United States and state jurisdictions where applicable. Our tax years for 2016 and forward are subject to examination by the U.S. tax authorities and our tax years for 2016 and forward are subject to examination by the California tax authorities due to carryforward of unutilized NOLs and research and development credits.

It is our practice to recognize interest and/or penalties related to income tax matters in income tax expense. For the years ended December 31, 2021, 2020 and 2019, the Company has not recognized any interest or penalties related to income taxes.

12. Net Loss Per Share

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

	As of December 31,		
	2021	2020	2019
Convertible preferred stock on an as-converted basis	—	—	24,385,388
Stock options to purchase common stock	5,757,957	3,655,945	2,516,470
Early exercised options subject to future vesting	90,146	339,385	621,053
RSU's subject to future vesting	335,196	162,930	—
ESPP shares subject to future issuance	12,219	3,733	—
Restricted stock subject to future vesting	—	—	137,863
Total	6,195,518	4,161,993	27,660,774

SIGNATURES

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

ARCUTIS BIOTHERAPEUTICS, INC.

Date: February 22, 2022

By: /s/ Todd Franklin Watanabe

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

Date: February 22, 2022

By: /s/ Scott L. Burrows

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Todd Franklin Watanabe, Scott L. Burrows and Mas Matsuda, his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or their, his or her substitutes or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Todd Franklin Watanabe Todd Franklin Watanabe	President, Chief Executive Officer and Director (Principal Executive Officer)	February 22, 2022
/s/ Scott L. Burrows Scott L. Burrows	Chief Financial Officer (Principal Accounting and Financial Officer)	February 22, 2022
/s/ Patrick J. Heron Patrick J. Heron	Director, Chairman	February 22, 2022
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri, Ph.D.	Director	February 22, 2022
/s/ Terrie Curran Terrie Curran	Director	February 22, 2022
/s/ Halley E. Gilbert Halley E. Gilbert	Director	February 22, 2022
/s/ Keith R. Leonard Keith R. Leonard	Director	February 22, 2022
/s/ Sue-Jean Lin Sue-Jean Lin	Director	February 22, 2022
/s/ Joseph Turner Joseph Turner	Director	February 22, 2022
/s/ Howard G. Welgus Howard G. Welgus, M.D.	Director	February 22, 2022

ARCUTIS BIOTHERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT INCENTIVE PLAN

1. PURPOSE. The purpose of this Plan is to provide incentives to attract, retain and motivate eligible employees whose potential contributions are important to the success of the Company, and any Subsidiaries that exist now or in the future, by offering them an opportunity to participate in the Company's future performance through the grant of Awards. Capitalized terms not defined elsewhere in the text are defined in Section 28.

2. SHARES SUBJECT TO THE PLAN.

2.1. Number of Shares Available. Subject to Section 2.4, Section 2.6 and Section 21 and any other applicable provisions hereof, the total number of Shares reserved and available for grant and issuance pursuant to this Plan as of the date of adoption of the Plan by the Board, is One Million, Two Hundred Fifty Thousand (1,250,000) Shares.

2.2. Lapsed, Returned Awards. Shares subject to Awards, and Shares issued under the Plan under any Award, will again be available for grant and issuance in connection with subsequent Awards under this Plan to the extent such Shares: (a) are subject to issuance upon exercise of an Option or SAR granted under this Plan but which cease to be subject to the Option or SAR for any reason other than exercise of the Option or SAR; (b) are subject to Awards granted under this Plan that are forfeited or are repurchased by the Company at the original issue price; (c) are subject to Awards granted under this Plan that otherwise terminate without such Shares being issued; or (d) are surrendered pursuant to an Exchange Program. To the extent an Award under the Plan is paid out in cash rather than Shares, such cash payment will not result in reducing the number of Shares available for issuance under the Plan. Shares used to pay the exercise price of an Award or withheld to satisfy the tax withholding obligations related to an Award will become available for future grant or sale under the Plan. For the avoidance of doubt, Shares that otherwise become available for grant and issuance because of the provisions of this Section 2.2 shall not include Shares subject to Awards that initially became available because of the substitution clause in Section 21.2 hereof.

2.3. Minimum Share Reserve. At all times the Company will reserve and keep available a sufficient number of Shares as will be required to satisfy the requirements of all outstanding Awards granted under this Plan.

2.4. Adjustment of Shares. If the number of outstanding Shares is changed by a stock dividend, extraordinary dividend or distribution (whether in cash, shares or other property, other than a regular cash dividend), recapitalization, stock split, reverse stock split, subdivision, combination, consolidation, reclassification, spin-off or similar change in the capital structure of the Company, without consideration, then (a) the number and class of Shares reserved for issuance and future grant under the Plan set forth in Section 2.1, (b) the Exercise Prices of and number and class of Shares subject to outstanding Options and SARs and (c) the number and class of Shares subject to other outstanding Awards will be proportionately adjusted, subject to any required action by the Board or the stockholders of the Company and in compliance with applicable securities laws; provided that fractions of a Share will not be issued.

If, by reason of an adjustment pursuant to this Section 2.4, a Participant's Award Agreement or other agreement related to any Award or the Shares subject to such Award covers additional or different shares of stock or securities, then such additional or different shares, and the Award Agreement or such other agreement in respect thereof, will be subject to all of the terms, conditions and restrictions which were applicable to the Award or the Shares subject to such Award prior to such adjustment.

3. ELIGIBILITY. All Awards may be granted to only to Eligible Employees.

4. ADMINISTRATION.

4.1. Committee Composition; Authority. This Plan will be administered by the Committee or by the Board acting as the Committee. Subject to the general purposes, terms and conditions of this Plan, and to the direction of the Board, the Committee will have full power to implement and carry out this Plan, except, however, the Board will establish the terms for the grant of an Award to Non-Employee Directors. The Committee will have the authority to:

(a) construe and interpret this Plan, any Award Agreement and any other agreement or document executed pursuant to this Plan;

(b) prescribe, amend and rescind rules and regulations relating to this Plan or any Award;

(c) select Eligible Employees to receive Awards;

(d) determine the form and terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder. Such terms and conditions include, but are not limited to, the Exercise Price, the time or times when Awards may vest and be exercised (which may be based on performance criteria) or settled, any vesting acceleration or waiver of forfeiture restrictions, the method to satisfy tax withholding obligations or any other tax liability legally due and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Committee will determine;

(e) determine the number of Shares or other consideration subject to Awards;

(f) determine the Fair Market Value in good faith and interpret the applicable provisions of this Plan and the definition of Fair Market Value in connection with circumstances that impact the Fair Market Value, if necessary;

(g) determine whether Awards will be granted singly, in combination with, in tandem with, in replacement of, or as alternatives to, other Awards under this Plan or any other incentive or compensation plan of the Company or any Subsidiary;

(h) grant waivers of Plan or Award conditions;

(i) determine the vesting, exercisability and payment of Awards;

(j) correct any defect, supply any omission or reconcile any inconsistency in this Plan, any Award or any Award Agreement;

(k) determine whether an Award has been vested and/or earned;

(l) determine the terms and conditions of any, and to institute any Exchange Program;

(m) reduce, waive or modify any criteria with respect to Performance Factors;

(n) adjust Performance Factors;

(o) adopt terms and conditions, rules and/or procedures (including the adoption of any subplan under this Plan) relating to the operation and administration of the Plan to accommodate requirements of local law and procedures outside of the United States or to qualify Awards for special tax treatment under laws of jurisdictions other than the United States;

(p) exercise discretion with respect to Performance Awards; and

(q) make all other determinations necessary or advisable for the administration of this Plan, including imposing, incidental to the grant of an Award, conditions with respect to the Award, including procedures to ensure that an Employee is eligible to participate in the Plan prior to the granting of any awards to such Employee under the Plan (including, without limitation, a requirement, if any, that each such Employee certify to the Company prior to the receipt of an award under the Plan that he or she has not been previously employed by the Company or a Subsidiary, or if previously employed, has had a bona fide period of non-employment, and that the grant of an award under the Plan is an inducement material to his or her agreement to enter into employment with the Company or a Subsidiary).

4.2. Committee Interpretation and Discretion. Any determination made by the Committee with respect to any Award will be made in its sole discretion at the time of grant of the Award or, unless in contravention of any express term of the Plan or Award, at any later time, and such determination will be final and binding on the Company and all persons having an interest in any Award under the Plan. Any dispute regarding the interpretation of the Plan or any Award Agreement will be submitted by the Participant or Company to the Committee for review. The resolution of such a dispute by the Committee will be final and binding on the Company and the Participant.

4.3. Documentation. The Award Agreement for a given Award, the Plan and any other documents may be delivered to, and accepted by, a Participant or any other person in any manner (including electronic distribution or posting) that meets applicable legal requirements.

4.4. Foreign Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws and practices in other countries in which the Company and its Subsidiaries operate or have Employees or other individuals eligible for Awards, the Committee, in its sole discretion, will have the power and authority to: (a) determine which Subsidiaries will be covered by the Plan; (b) determine which individuals outside the United States are eligible to participate in the Plan; (c) modify the terms and conditions of any Award granted to individuals outside the United States or foreign nationals to comply with applicable foreign laws, policies, customs and practices; (d) establish subplans and modify exercise procedures, vesting conditions, and other terms and procedures, to the extent the Committee determines such actions to be necessary or advisable (and such subplans and/or modifications will be attached to this Plan as appendices, if necessary); provided, however, that no such subplans and/or modifications will increase the share limitations contained in Section 2.1 hereof; and (e) take any action, before or after an Award is made, that the Committee determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no Awards will be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

5. OPTIONS. An Option is the right but not the obligation to purchase a Share, subject to certain conditions, if applicable. The Committee may grant Options to Eligible Employees (such Options shall be Nonqualified Stock Options ("***NSOs***")) and may determine the number of Shares subject to the Option, the Exercise Price of the Option, the period during which the Option may vest and be exercised, and all other terms and conditions of the Option, subject to the following terms of this section.

5.1. Option Grant. An Option may be, but need not be, awarded upon satisfaction of such Performance Factors during any Performance Period as are set out in advance in the Participant's individual Award Agreement. If the Option is being earned upon the satisfaction of Performance Factors, then the Committee will: (a) determine the nature, length and starting date of any Performance Period for each Option; and (b) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to Options that are subject to different performance goals and other criteria.

5.2. Date of Grant. The date of grant of an Option will be the date on which the Committee makes the determination to grant such Option, or a specified future date. The Award Agreement will be delivered to the Participant within a reasonable time after the granting of the Option.

5.3. Exercise Period. Options may be vested and exercisable within the times or upon the conditions as set forth in the Award Agreement governing such Option; provided, however, that no Option will be exercisable after the expiration of ten (10) years from the date the Option is granted. The Committee also may provide for Options to become exercisable at one time or from time to time, periodically or otherwise, in such number of Shares or percentage of Shares as the Committee determines.

5.4. Exercise Price. The Exercise Price of an Option will be determined by the Committee when the Option is granted; provided that the Exercise Price of an Option will be not less than one hundred percent (100%) of the Fair Market Value of the Shares on the date of grant. Payment for the Shares purchased may be made in accordance with Section 11 and the Award Agreement and in accordance with any procedures established by the Company.

5.5. Method of Exercise. Any Option granted hereunder will be vested and exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Committee and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share. An Option will be deemed exercised when the Company receives: (a) notice of exercise (in such form as the Committee may specify from time to time) from the person entitled to exercise the Option (and/or via electronic execution through the authorized third-party administrator), and (b) full payment for the Shares with respect to which the Option is exercised (together with applicable withholding taxes). Full payment may consist of any consideration and method of payment authorized by the Committee and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Option will be issued in the name of the Participant. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 2.4 of the Plan. Exercising an Option in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.

5.6. Termination of Service. If the Participant's Service terminates for any reason except for Cause or the Participant's death or Disability, then the Participant may exercise such Participant's Options only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates no later than three (3) months after the date Participant's Service terminates (or such shorter or longer time period as may be determined by the Committee), but in any event no later than the expiration date of the Options.

(a) Death. If the Participant's Service terminates because of the Participant's death (or the Participant dies within three (3) months after Participant's Service terminates other than for Cause or because of the Participant's Disability), then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the Participant's legal representative, or authorized assignee, no later than twelve (12) months after the date Participant's Service terminates (or such shorter time period or longer time period as may be determined by the Committee), but in any event no later than the expiration date of the Options.

(b) Disability. If the Participant's Service terminates because of the Participant's Disability, then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the Participant (or the Participant's legal representative or authorized assignee) no later than

twelve (12) months after the date Participant's Service terminates (or such shorter or longer time period as may be determined by the Committee), but in any event no later than the expiration date of the Options.

(c) Cause. If the Participant's Service terminates for Cause, then Participant's Options (whether or not vested) will expire on the date of termination of Participant's Service if the Committee has reasonably determined in good faith that such cessation of Services has resulted in connection with an act or failure to act constituting Cause (or such Participant's Services could have been terminated for Cause (without regard to the lapsing of any required notice or cure periods in connection therewith) at the time such Participant terminated Services), or at such later time and on such conditions as are determined by the Committee, but in any event no later than the expiration date of the Options. Unless otherwise provided in an employment agreement, Award Agreement, or other applicable agreement, Cause will have the meaning set forth in the Plan.

5.7. Limitations on Exercise. The Committee may specify a minimum number of Shares that may be purchased on any exercise of an Option, provided that such minimum number will not prevent any Participant from exercising the Option for the full number of Shares for which it is then exercisable.

5.8. Modification, Extension or Renewal. The Committee may modify, extend or renew outstanding Options and authorize the grant of new Options in substitution therefor, provided that any such action may not, without the written consent of a Participant, impair any of such Participant's rights under any Option previously granted. Subject to Section 17 of this Plan, by written notice to affected Participants, the Committee may reduce the Exercise Price of outstanding Options without the consent of such Participants; provided, however, that the Exercise Price may not be reduced below the Fair Market Value on the date the action is taken to reduce the Exercise Price.

6. RESTRICTED STOCK AWARDS. A Restricted Stock Award is an offer by the Company to sell to an Eligible Employee Shares that are subject to restrictions ("***Restricted Stock***"). The Committee will determine to whom an offer will be made, the number of Shares the Participant may purchase, the Purchase Price, the restrictions under which the Shares will be subject and all other terms and conditions of the Restricted Stock Award, subject to the Plan.

6.1. Restricted Stock Purchase Agreement. All purchases under a Restricted Stock Award will be evidenced by an Award Agreement. Except as may otherwise be provided in an Award Agreement, a Participant accepts a Restricted Stock Award by signing and delivering to the Company an Award Agreement with full payment of the Purchase Price, within thirty (30) days from the date the Award Agreement was delivered to the Participant. If the Participant does not accept such Award within thirty (30) days, then the offer of such Restricted Stock Award will terminate, unless the Committee determines otherwise.

6.2. Purchase Price. The Purchase Price for a Restricted Stock Award will be determined by the Committee and may be less than Fair Market Value on the date the Restricted Stock Award is granted. Payment of the Purchase Price must be made in accordance with Section 11 of the Plan, and the Award Agreement and in accordance with any procedures established by the Company.

6.3. Terms of Restricted Stock Awards. Restricted Stock Awards will be subject to such restrictions as the Committee may impose or are required by law. These restrictions may be based on completion of a specified number of years of service with the Company or upon completion of Performance Factors, if any, during any Performance Period as set out in advance in the Participant's Award Agreement. Prior to the grant of a Restricted Stock Award, the Committee shall: (a) determine the nature, length and starting date of any Performance Period for the Restricted Stock Award; (b) select from among the Performance Factors to be used to measure performance goals, if any; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Restricted Stock Awards that are subject to different Performance Periods and having different performance goals and other criteria.

6.4. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

7. STOCK BONUS AWARDS. A Stock Bonus Award is an award to an Eligible Employee of Shares for Services to be rendered or for past Services already rendered to the Company or any Subsidiary. All Stock Bonus Awards shall be made pursuant to an Award Agreement. No payment from the Participant will be required for Shares awarded pursuant to a Stock Bonus Award.

7.1. Terms of Stock Bonus Awards. The Committee will determine the number of Shares to be awarded to the Participant under a Stock Bonus Award and any restrictions thereon. These restrictions may be based upon completion of a specified number of years of service with the Company or upon satisfaction of performance goals based on Performance Factors during any Performance Period as set out in advance in the Participant's Stock Bonus Agreement. Prior to the grant of any Stock Bonus Award the Committee shall: (a) determine the nature, length and starting date of any Performance Period for the Stock Bonus Award; (b) select from among the Performance Factors to be used to measure performance goals; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Stock Bonus Awards that are subject to different Performance Periods and different performance goals and other criteria.

7.2. Form of Payment to Participant. Payment may be made in the form of cash, whole Shares, or a combination thereof, based on the Fair Market Value of the Shares earned under a Stock Bonus Award on the date of payment, as determined in the sole discretion of the Committee.

7.3. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

8. STOCK APPRECIATION RIGHTS. A Stock Appreciation Right ("***SAR***") is an award to an Eligible Employee that may be settled in cash, or Shares (which may consist of Restricted Stock), having a value equal to (a) the difference between the Fair Market Value on the date of exercise less the Exercise Price multiplied by (b) the number of Shares with respect to which the SAR is being settled (subject to any maximum number of Shares that may be issuable as specified in an Award Agreement). All SARs shall be made pursuant to an Award Agreement.

8.1. Terms of SARs. The Committee will determine the terms of each SAR including, without limitation: (a) the number of Shares subject to the SAR; (b) the Exercise Price and the time or times during which the SAR may be settled; (c) the consideration to be distributed on settlement of the SAR; and (d) the effect of the Participant's termination of Service on each SAR. The Exercise Price of the SAR will be determined by the Committee when the SAR is granted, and may not be less than Fair Market Value. A SAR may be awarded upon satisfaction of Performance Factors, if any, during any Performance Period as are set out in advance in the Participant's individual Award Agreement. If the SAR is being earned upon the satisfaction of Performance Factors, then the Committee will: (x) determine the nature, length and starting date of any Performance Period for each SAR; and (y) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to SARs that are subject to different Performance Factors and other criteria.

8.2. Exercise Period and Expiration Date. A SAR will be exercisable within the times or upon the occurrence of events determined by the Committee and set forth in the Award Agreement governing such SAR. The SAR Agreement shall set forth the expiration date; provided that no SAR will be exercisable after the expiration of ten (10) years from the date the SAR is granted. The Committee may also provide for SARs to become exercisable at one time or from time to time, periodically or

otherwise (including, without limitation, upon the attainment during a Performance Period of performance goals based on Performance Factors), in such number of Shares or percentage of the Shares subject to the SAR as the Committee determines. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee). Notwithstanding the foregoing, the rules of Section 5.6 also will apply to SARs.

8.3. Form of Settlement. Upon exercise of a SAR, a Participant will be entitled to receive payment from the Company in an amount determined by multiplying (a) the difference between the Fair Market Value of a Share on the date of exercise less the Exercise Price; times (b) the number of Shares with respect to which the SAR is exercised. At the discretion of the Committee, the payment from the Company for the SAR exercise may be in cash, in Shares of equivalent value, or in some combination thereof. The portion of a SAR being settled may be paid currently or on a deferred basis with such interest, if any, as the Committee determines, provided that the terms of the SAR and any deferral satisfy the requirements of Section 409A of the Code to the extent applicable.

8.4. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

9. RESTRICTED STOCK UNITS. A Restricted Stock Unit ("***RSU***") is an award to an Eligible Employee covering a number of Shares that may be settled in cash, or by issuance of those Shares (which may consist of Restricted Stock). All RSUs shall be made pursuant to an Award Agreement.

9.1. Terms of RSUs. The Committee will determine the terms of an RSU including, without limitation: (a) the number of Shares subject to the RSU; (b) the time or times during which the RSU may be settled; (c) the consideration to be distributed on settlement; and (d) the effect of the Participant's termination of Service on each RSU; provided that no RSU shall have a term longer than ten (10) years. An RSU may be awarded upon satisfaction of such performance goals based on Performance Factors during any Performance Period as are set out in advance in the Participant's Award Agreement. If the RSU is being earned upon satisfaction of Performance Factors, then the Committee will: (x) determine the nature, length and starting date of any Performance Period for the RSU; (y) select from among the Performance Factors to be used to measure the performance, if any; and (z) determine the number of Shares deemed subject to the RSU. Performance Periods may overlap and Participants may participate simultaneously with respect to RSUs that are subject to different Performance Periods and different performance goals and other criteria.

9.2. Form and Timing of Settlement. Payment of earned RSUs shall be made as soon as practicable after the date(s) determined by the Committee and set forth in the Award Agreement. The Committee, in its sole discretion, may settle earned RSUs in cash, Shares, or a combination of both. The Committee may also permit a Participant to defer payment under an RSU to a date or dates after the RSU is earned provided that the terms of the RSU and any deferral satisfy the requirements of Section 409A of the Code to the extent applicable.

9.3. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

10. PERFORMANCE AWARDS. A Performance Award is an award to an Eligible Employee that is based upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee, and may be settled in cash, Shares (which may consist of, without limitation, Restricted Stock), other property, or any combination thereof. Grants of Performance Awards shall be made pursuant to an Award Agreement.

10.1. Performance Awards shall include Performance Shares, Performance Units, and cash-based Awards as set forth in Sections 10.1(a), 10.1(b), and 10.1(c) below.

(a) Performance Shares. The Committee may grant Awards of Performance Shares, designate the Participants to whom Performance Shares are to be awarded and determine the number of Performance Shares and the terms and conditions of each such Award. Performance Shares shall consist of a unit valued by reference to a designated number of Shares, the value of which may be paid to the Participant by delivery of Shares or, if set forth in the instrument evidencing the Award, of such property as the Committee shall determine, including, without limitation, cash, Shares, other property, or any combination thereof, upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee. The amount to be paid under an Award of Performance Shares may be adjusted on the basis of such further consideration as the Committee shall determine in its sole discretion.

(b) Performance Units. The Committee may grant Awards of Performance Units, designate the Participants to whom Performance Units are to be awarded and determine the number of Performance Units and the terms and conditions of each such Award. Performance Units shall consist of a unit valued by reference to a designated amount of property other than Shares, which value may be paid to the Participant by delivery of such property as the Committee shall determine, including, without limitation, cash, Shares, other property, or any combination thereof, upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee.

(c) Cash-Settled Performance Awards. The Committee may grant cash-settled Performance Awards to Participants under the terms of this Plan. Such awards will be based on the attainment of performance goals using the Performance Factors within this Plan that are established by the Committee for the relevant performance period.

10.2. Terms of Performance Awards. Performance Awards will be based on the attainment of performance goals using the Performance Factors within this Plan that are established by the Committee for the relevant Performance Period. The Committee will determine, and each Award Agreement shall set forth, the terms of each Performance Award including, without limitation: (a) the amount of any cash bonus, (b) the number of Shares deemed subject to an award of Performance Shares; (c) the Performance Factors and Performance Period that shall determine the time and extent to which each award of Performance Shares shall be settled; (d) the consideration to be distributed on settlement, and (e) the effect of the Participant's termination of Service on each Performance Award. In establishing Performance Factors and the Performance Period the Committee will: (x) determine the nature, length and starting date of any Performance Period; (y) select from among the Performance Factors to be used; and (z) determine the number of Shares deemed subject to the award of Performance Shares. Prior to settlement the Committee shall determine the extent to which Performance Awards have been earned. Performance Periods may overlap, and Participants may participate simultaneously with respect to Performance Awards that are subject to different Performance Periods and different performance goals and other criteria.

10.3. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee).

11. PAYMENT FOR SHARE PURCHASES. Payment from a Participant for Shares purchased pursuant to this Plan may be made in cash or by check or, where approved for the Participant by the Committee and where permitted by law (and to the extent not otherwise set forth in the applicable Award Agreement):

(a) by cancellation of indebtedness of the Company to the Participant;

(b) by surrender of shares of the Company held by the Participant that have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which said Award will be exercised or settled;

(c) by waiver of compensation due or accrued to the Participant for services rendered or to be rendered to the Company or a Subsidiary;

(d) by consideration received by the Company pursuant to a broker-assisted or other form of cashless exercise program implemented by the Company in connection with the Plan;

(e) by any combination of the foregoing; or

(f) by any other method of payment as is permitted by applicable law.

12. WITHHOLDING TAXES.

12.1. Withholding Generally. Whenever Shares are to be issued in satisfaction of Awards granted under this Plan or a tax event occurs, the Company may require the Participant to remit to the Company or to the Subsidiary, as applicable, employing the Participant, an amount sufficient to satisfy applicable U.S. federal, state, local and international tax or any other tax or social insurance liability (the "***Tax-Related Items***") required to be withheld from the Participant prior to the delivery of Shares pursuant to exercise or settlement of any Award. Whenever payments in satisfaction of Awards granted under this Plan are to be made in cash, such payment will be net of an amount sufficient to satisfy applicable withholding obligations for Tax-Related Items. Unless otherwise determined by the Committee, the Fair Market Value of the Shares will be determined as of the date that the taxes are required to be withheld and such Shares will be valued based on the value of the actual trade or, if there is none, the Fair Market Value of the Shares as of the previous trading day.

12.2. Stock Withholding. The Committee, or its delegate(s), as permitted by applicable law, in its sole discretion and pursuant to such procedures as it may specify from time to time and to limitations of local law, may require or permit a Participant to satisfy such Tax Related Items legally due from the Participant, in whole or in part by (without limitation) (a) paying cash, (b) having the Company withhold otherwise deliverable cash or Shares having a Fair Market Value equal to the Tax-Related Items to be withheld, (c) delivering to the Company already-owned shares having a Fair Market Value equal to the Tax-Related Items to be withheld or (d) withholding from the proceeds of the sale of otherwise deliverable Shares acquired pursuant to an Award either through a voluntary sale or through a mandatory sale arranged by the Company. The Company may withhold or account for these Tax-Related Items by considering applicable statutory withholding rates or other applicable withholding rates, including up to (but not in excess of) the maximum permissible statutory tax rate for the applicable tax jurisdiction, to the extent consistent with applicable laws.

13. TRANSFERABILITY. Unless determined otherwise by the Committee, an Award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution. If the Committee makes an Award transferable, including, without limitation, by instrument to an inter vivos or testamentary trust in which the Awards are to be passed to beneficiaries upon the death of the trustor (settlor) or by gift or by domestic relations order to a Permitted Transferee, such Award will contain such additional terms and conditions as the Committee deems appropriate. All Awards will be exercisable: (a) during the Participant's lifetime only by the Participant, or the Participant's guardian or legal representative; (b) after the Participant's death, by the legal representative of the Participant's heirs or legatees; and (c) by a Permitted Transferee.

14. PRIVILEGES OF STOCK OWNERSHIP; RESTRICTIONS ON SHARES.

14.1. Voting and Dividends. No Participant will have any of the rights of a stockholder with respect to any Shares until the Shares are issued to the Participant, except for any Dividend Equivalent Rights permitted by an applicable Award Agreement. Any Dividend Equivalent Rights will be subject to the same vesting or performance conditions as the underlying Award. In addition, the Committee may provide that any Dividend Equivalent Rights permitted by an applicable Award Agreement will be deemed to have been reinvested in additional Shares or otherwise reinvested. After Shares are issued to the Participant, the Participant will be a stockholder and have all the rights of a stockholder with respect to such Shares, including the right to vote and receive all dividends or other distributions made or paid with respect to such Shares; provided, that if such Shares are Restricted Stock, then any new, additional or different securities the Participant may become entitled to receive with respect to such Shares by virtue of a stock dividend, stock split or any other change in the corporate or capital structure of the Company will be subject to the same restrictions as the Restricted Stock; provided, further, that the Participant will have no right to such stock dividends or stock distributions with respect to Unvested Shares, and any such dividends or stock distributions will be accrued and paid only at such time, if any, as such Unvested Shares become vested Shares. The Committee, in its discretion, may provide in the Award Agreement evidencing any Award that the Participant will be entitled to Dividend Equivalent Rights with respect to the payment of cash dividends on Shares underlying an Award during the period beginning on the date the Award is granted and ending, with respect to each Share subject to the Award, on the earlier of the date on which the Award is exercised or settled or the date on which it is forfeited provided, that no Dividend Equivalent Right will be paid with respect to the Unvested Shares, and such dividends or stock distributions will be accrued and paid only at such time, if any, as such Unvested Shares become vested Shares. Such Dividend Equivalent Rights, if any, will be credited to the Participant in the form of additional whole Shares as of the date of payment of such cash dividends on Shares.

14.2. Restrictions on Shares. At the discretion of the Committee, the Company may reserve to itself and/or its assignee(s) a right to repurchase (a "***Right of Repurchase***") a portion of any or all Unvested Shares held by a Participant following such Participant's termination of Service at any time within ninety (90) days (or such longer or shorter time determined by the Committee) after the later of the date Participant's Service terminates and the date the Participant purchases Shares under this Plan, for cash and/or cancellation of purchase money indebtedness, at the Participant's Purchase Price or Exercise Price, as the case may be.

15. CERTIFICATES. All Shares or other securities whether or not certificated, delivered under this Plan will be subject to such stock transfer orders, legends and other restrictions as the Committee may deem necessary or advisable, including restrictions under any applicable U.S. federal, state or foreign securities law, or any rules, regulations and other requirements of the SEC or any stock exchange or automated quotation system upon which the Shares may be listed or quoted and any non-U.S. exchange controls or securities law restrictions to which the Shares are subject.

16. ESCROW; PLEDGE OF SHARES. To enforce any restrictions on a Participant's Shares, the Committee may require the Participant to deposit all certificates representing Shares, together with stock powers or other instruments of transfer approved by the Committee, appropriately endorsed in blank, with the Company or an agent designated by the Company to hold in escrow until such restrictions have lapsed or terminated, and the Committee may cause a legend or legends referencing such restrictions to be placed on the certificates. Any Participant who is permitted to execute a promissory note as partial or full consideration for the purchase of Shares under this Plan will be required to pledge and deposit with the Company all or part of the Shares so purchased as collateral to secure the payment of the Participant's obligation to the Company under the promissory note; provided, however, that the Committee may require or accept other or additional forms of collateral to secure the payment of such obligation and, in any event, the Company will have full recourse against the Participant under the promissory note notwithstanding any pledge of the Participant's Shares or other collateral. In connection with any pledge of the Shares, the Participant will be required to execute and deliver a written pledge agreement in such form as the Committee will from time to time approve. The Shares purchased with the promissory note may be released from the pledge on a pro rata basis as the promissory note is paid.

17. REPRICING; EXCHANGE AND BUYOUT OF AWARDS. Without prior stockholder approval, the Committee may (a) reprice Options or SARs (and where such repricing is a reduction in the Exercise Price of outstanding Options or SARs, the consent of the affected Participants is not required provided written notice is provided to them, notwithstanding any adverse tax consequences to them arising from the repricing), and (b) with the consent of the respective Participants (unless not required pursuant to Section 5.9 of the Plan), pay cash or issue new Awards in exchange for the surrender and cancellation of any, or all, outstanding Awards.

18. SECURITIES LAW AND OTHER REGULATORY COMPLIANCE. An Award will not be effective unless such Award is in compliance with all applicable U.S. and foreign federal and state securities and exchange control laws, rules and regulations of any governmental body, and the requirements of any stock exchange or automated quotation system upon which the Shares may then be listed or quoted, as they are in effect on the date of grant of the Award and also on the date of exercise or other issuance. Notwithstanding any other provision in this Plan, the Company will have no obligation to issue or deliver certificates for Shares under this Plan prior to: (a) obtaining any approvals from governmental agencies that the Company determines are necessary or advisable; and/or (b) completion of any registration or other qualification of such Shares under any state or federal or foreign law or ruling of any governmental body that the Company determines to be necessary or advisable. The Company will be under no obligation to register the Shares with the SEC or to effect compliance with the registration, qualification or listing requirements of any foreign or state securities laws, exchange control laws, stock exchange or automated quotation system, and the Company will have no liability for any inability or failure to do so.

19. NO OBLIGATION TO EMPLOY. Nothing in this Plan or any Award granted under this Plan will confer or be deemed to confer on any Participant any right to continue in the employ of, or to continue any other relationship with, the Company or any Subsidiary or limit in any way the right of the Company or any Subsidiary to terminate Participant's employment or other relationship at any time.

20. CORPORATE TRANSACTIONS.

20.1. Assumption or Replacement of Awards by Successor. In the event of a Corporate Transaction any or all outstanding Awards may be (a) continued by the Company, if the Company is the successor entity; or (b) assumed or substituted by the successor corporation, or a parent or subsidiary of the successor corporation, for substantially equivalent Awards (including, but not limited to, a payment in cash or the right to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), in each case after taking into account appropriate adjustments for the number and kind of shares and exercise prices. The successor corporation may also issue, as replacement of outstanding Shares of the Company held by the Participant, substantially similar shares or other property subject to repurchase restrictions no less favorable to the Participant. In the event such successor corporation refuses to assume, substitute or replace any Award in accordance with this Section 20, then notwithstanding any other provision in this Plan to the contrary, each such Award shall become fully vested and, as applicable, exercisable and any rights of repurchase or forfeiture restrictions thereon shall lapse, immediately prior to the consummation of the Corporation Transaction. Performance Awards not assumed pursuant to the foregoing shall be deemed earned and vested at 100% of target level, unless otherwise indicated pursuant to the terms and conditions of the applicable Award Agreement.

If an Award vests in lieu of assumption or substitution in connection with a Corporate Transaction as provided above, the Committee will notify the holder of such Award in writing or electronically that such Award will be exercisable for a period of time determined by the Committee in its sole discretion, and such Award will terminate upon the expiration of such period without consideration. Any determinations by the Committee need not treat all outstanding Awards in an identical manner, and shall be final and binding on each applicable Participant.

20.2. Assumption of Awards by the Company. The Company, from time to time, also may substitute or assume outstanding awards granted by another company, whether in connection with an acquisition of such other company or otherwise, by either; (a) granting an Award under this Plan in substitution of such other company's award; or (b) assuming such award as if it had been granted under this Plan if the terms of such assumed award could be applied to an Award granted under this Plan. Such substitution or assumption will be permissible if the holder of the substituted or assumed award would have been eligible to be granted an Award under this Plan if the other company had applied the rules of this Plan to such grant. In the event the Company assumes an award granted by another company, the terms and conditions of such award will remain unchanged. In the event the Company elects to grant a new Option in substitution rather than assuming an existing option, such new Option may be granted with a similarly adjusted Exercise Price. Substitute Awards will not reduce the number of Shares authorized for grant under the Plan or authorized for grant to a Participant in a calendar year.

21. ADOPTION AND STOCKHOLDER APPROVAL NOT REQUIRED. The Plan will become effective on the date the Board has adopted the Plan (the "***Effective Date***"). It is expressly intended that approval of the Company's stockholders not be required as a condition of the effectiveness of the Plan, and the Plan's provisions shall be interpreted in a manner consistent with such intent for all purposes. Specifically, Nasdaq Stock Market Rule 5635(c) generally requires stockholder approval for stock option plans or other equity compensation arrangements adopted by companies whose securities are listed on the Nasdaq Stock Market pursuant to which stock awards or stock may be acquired by officers, directors, employees, or consultants of such companies. Nasdaq Stock Market Rule 5635(c)(4) provides an exception to this requirement for issuances of securities to a person not previously an employee or director of the issuer, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the issuer; provided, such issuances are approved by either the issuer's compensation committee comprised of a majority of independent directors or a majority of the issuer's independent directors. Notwithstanding anything to the contrary herein, awards under the Plan may only be made to employees who have not previously been an employee or director of the Company or a Subsidiary, or following a bona fide period of non-employment by the Company or a Subsidiary, as an inducement material to the employee's entering into employment with the Company or a Subsidiary. Awards under the Plan will be approved by (i) the Compensation Committee of the Board, comprised of Non-Employee Directors or (ii) a majority of the Company's Non-Employee Directors. Accordingly, pursuant to Nasdaq Stock Market Rule 5635(c)(4), the issuance of Awards and the Shares issuable upon exercise or vesting of such Awards pursuant to the Plan are not subject to the approval of the Company's stockholders.

22. GOVERNING LAW. This Plan and all Awards granted hereunder will be governed by and construed in accordance with the laws of the State of Delaware (excluding its conflict of laws rules).

23. AMENDMENT OR TERMINATION OF PLAN. The Board may at any time terminate or amend this Plan in any respect, including, without limitation, amendment of any form of Award Agreement or instrument to be executed pursuant to this Plan; provided, however, that the Board will not, without the approval of the stockholders of the Company, amend this Plan in any manner that requires such stockholder approval; provided further, that a Participant's Award will be governed by the version of this Plan then in effect at the time such Award was granted. No termination or amendment of the Plan or any outstanding Award may adversely affect any then outstanding Award without the consent of the Participant, unless such termination or amendment is necessary to comply with applicable law, regulation or rule.

24. NONEXCLUSIVITY OF THE PLAN. Neither the adoption of this Plan by the Board, the submission of this Plan to the stockholders of the Company for approval, nor any provision of this Plan will be construed as creating any limitations on the power of the Board to adopt such additional compensation arrangements as it may deem desirable, including, without limitation, the granting of stock awards and bonuses otherwise than under this Plan, and such arrangements may be either generally applicable or applicable only in specific cases.

25. **INSIDER TRADING POLICY**. Each Participant who receives an Award will comply with any policy adopted by the Company from time to time covering transactions in the Company's securities by Employee and/or officers of the Company, as well as with any applicable insider trading or market abuse laws to which the Participant may be subject.

26. **ALL AWARDS SUBJECT TO COMPANY CLAWBACK OR RECOUPMENT POLICY**. All Awards, subject to applicable law, shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of Participant's employment with the Company that is applicable to Employees of the Company, and in addition to any other remedies available under such policy and applicable law, may require the cancellation of outstanding Awards and the recoupment of any gains realized with respect to Awards.

27. **DEFINITIONS**. As used in this Plan, and except as elsewhere defined herein, the following terms will have the following meanings:

27.1. "***Award***" means any award under the Plan, including any Option, Restricted Stock, Stock Bonus, Stock Appreciation Right, Restricted Stock Unit or Performance Award.

27.2. "***Award Agreement***" means, with respect to each Award, the written or electronic agreement between the Company and the Participant setting forth the terms and conditions of the Award, and country-specific appendix thereto for grants to non-U.S. Participants, which will be in substantially a form (which need not be the same for each Participant) that the Committee (or in the case of Award agreements that are not used for Insiders, the Committee's delegate(s)) has from time to time approved, and will comply with and be subject to the terms and conditions of this Plan.

27.3. "***Board***" means the Board of Directors of the Company.

27.4. "***Cause***" means a determination by the Company (and in the case of Participant who is subject to Section 16 of the Exchange Act, the Committee) that the Participant has committed an act or acts constituting any of the following: (a) dishonesty, fraud, misconduct or negligence in connection with Participant's duties to the Company, (b) unauthorized disclosure or use of the Company's confidential or proprietary information or trade secrets, (c) misappropriation of a business opportunity of the Company, (d) materially aiding Company competitor, (e) a conviction or plea of nolo contendere to a felony or crime involving moral turpitude, (f) failure or refusal to attend to the duties or obligations of the Participant's position (g) violation or breach of, or failure to comply with, the Company's code of ethics or conduct, any of the Company's rules, policies or procedures applicable to the Participant or any agreement in effect between the Company and the Participant or (h) other conduct by such Participant that could be expected to be harmful to the business, interests or reputation of the Company. The determination as to whether Cause for a Participant's termination exists will be made in good faith by the Company and will be final and binding on the Participant. This definition does not in any way limit the Company's or any Subsidiary's ability to terminate a Participant's employment or services at any time as provided in Section 19 above. Notwithstanding the foregoing, the foregoing definition of "Cause" may, in part or in whole, be modified or replaced in each individual employment agreement, Award Agreement, or other applicable agreement with any Participant provided that such document specifically supersedes this definition.

27.5. "***Code***" means the United States Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

27.6. "***Committee***" means the Compensation Committee of the Board or the Board. Any action taken by the Board as the Committee in connection with the administration of the Plan shall not be deemed approved by the Board unless such actions are approved by a majority of the Non-Employee Directors of the Board.

27.7. "***Company***" means Arcutis Biotherapeutics, Inc., a Delaware corporation, or any successor corporation.

27.8. "***Corporate Transaction***" means the occurrence of any of the following events: (a) 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; provided, however, that for purposes of this subclause (a) the acquisition of additional securities by any one Person who is considered to own more than fifty percent (50%) of the total voting power of the securities of the Company will not be considered a Corporate Transaction; (b) the consummation of the sale or disposition by the Company of all or substantially all of the Company's assets; (c) 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; (d) any other transaction which qualifies as a "corporate transaction" under Section 424(a) of the Code wherein the stockholders of the Company give up all of their equity interest in the Company (except for the acquisition, sale or transfer of all or substantially all of the outstanding shares of the Company) or (e) a change in the effective control of the Company that occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purpose of this subclause (e), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Corporate Transaction. For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company. Notwithstanding the foregoing, to the extent that any amount constituting deferred compensation (as defined in Section 409A of the Code) would become payable under this Plan by reason of a Corporate Transaction, such amount will become payable only if the event constituting a Corporate Transaction would also qualify as a change in ownership or effective control of the Company or a change in the ownership of a substantial portion of the assets of the Company, each as defined within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and IRS guidance that has been promulgated or may be promulgated thereunder from time to time.

27.9. "***Disability***" means that the Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than 12 months.

27.10. "***Dividend Equivalent Right***" means the right of a Participant, granted at the discretion of the Committee or as otherwise provided by the Plan, to receive a credit for the account of such Participant in an amount equal to the cash, stock or other property dividends in amounts equivalent to cash, stock or other property dividends for each Share represented by an Award held by such Participant.

27.11. "***Eligible Employee***" means any Employee who has not previously been an employee or director of the Company or a Subsidiary, or is commencing employment with the Company or a Subsidiary following a bona fide period of non-employment by the Company or a Subsidiary, if he or she is granted an award in connection with his or her commencement of employment with the Company or a Subsidiary and such grant is an inducement material to his or her entering into employment with the Company or a Subsidiary. The Committee may in its discretion adopt procedures from time to time to ensure that an Employee is eligible to participate in the Plan prior to the granting of any awards to such Employee under the Plan (including, without limitation, a requirement, that each such Employee certify to the Company prior to the receipt of an award under the Plan that he or she has not been previously

employed by the Company or a Subsidiary, or if previously employed, has had a bona fide period of non-employment, and that the grant of an award under the Plan is an inducement material to his or her agreement to enter into employment with the Company or a Subsidiary).

27.12. "***Employee***" means any person, including officers, providing services as an employee to the Company or any Subsidiary. Neither service as a Non-Employee Director nor payment of a director's fee by the Company will be sufficient to constitute "employment" by the Company.

27.13. "***Exchange Act***" means the United States Securities Exchange Act of 1934, as amended.

27.14. "***Exchange Program***" means a program pursuant to which (a) outstanding Awards are surrendered, cancelled or exchanged for cash, the same type of Award or a different Award (or combination thereof) or (b) the exercise price of an outstanding Award is increased or reduced, each as described in Section 17.

27.15. "***Exercise Price***" means, with respect to an Option, the price at which a holder may purchase the Shares issuable upon exercise of an Option and with respect to a SAR, the price at which the SAR is granted to the holder thereof.

27.16. "***Fair Market Value***" means, as of any date, the value of a share of the Company's common stock determined as follows:

(a) if such common stock is publicly traded and is then listed on a national securities exchange, its closing price on the date of determination on the principal national securities exchange on which the common stock is listed or admitted to trading as reported in *The Wall Street* Journal or such other source as the Committee deems reliable;

(b) if such common stock is publicly traded but is neither listed nor admitted to trading on a national securities exchange, the average of the closing bid and asked prices on the date of determination as reported in *The Wall Street Journal* or such other source as the Committee deems reliable; or

(c) by the Board or the Committee in good faith.

27.17. "***Insider***" means an officer or director of the Company or any other person whose transactions in the Company's common stock are subject to Section 16 of the Exchange Act.

27.18. "***IRS***" means the United States Internal Revenue Service.

27.19. "***Non-Employee Director***" means a Director who is not an officer or Employee.

27.20. "***Option***" means an Award as defined in Section 5 and granted under the Plan.

27.21. "***Participant***" means a person who holds an Award under this Plan.

27.22. *"**Performance Award**"* means an Award as defined in Section 10 and granted under the Plan.

27.23. *"**Performance Factors**"* means any of the factors selected by the Committee and specified in an Award Agreement, from among the following objective or subjective measures, either individually, alternatively or in any combination applied to the Participant, the Company, any business unit or Subsidiary, either individually, alternatively, or in any combination, on a GAAP or non-GAAP basis, and measured, to the extent applicable on an absolute basis or relative to a pre-established target, to

determine whether the performance goals established by the Committee with respect to applicable Awards have been satisfied:

(a) Profit Before Tax;

(b) Sales;

(c) Expenses;

(d) Billings;

(e) Revenue;

(f) Net revenue;

(g) Earnings (which may include earnings before interest and taxes, earnings before taxes, net earnings, stock-based compensation expenses, depreciation and amortization);

(h) Operating income;

(i) Operating margin;

(j) Operating profit;

(k) Controllable operating profit, or net operating profit;

(l) Net Profit;

(m) Gross margin;

(n) Operating expenses or operating expenses as a percentage of revenue;

(o) Net income;

(p) Earnings per share;

(q) Total stockholder return;

(r) Market share;

(s) Return on assets or net assets;

(t) The Company's stock price;

(u) Growth in stockholder value relative to a pre-determined index;

(v) Return on equity;

(w) Return on invested capital;

(x) Cash Flow (including free cash flow or operating cash flows);

(y) Balance of cash, cash equivalents and marketable securities;

(z) Cash conversion cycle;

(aa) Economic value added;

(bb) Individual confidential business objectives;

(cc) Contract awards or backlog;

(dd) Overhead or other expense reduction;

(ee) Credit rating;

(ff) Completion of an identified special project;

(gg) Completion of a joint venture or other corporate transaction;

(hh) Strategic plan development and implementation;

(ii) Succession plan development and implementation;

(jj) Improvement in workforce diversity;

(kk) Employee satisfaction;

(ll) Employee retention;

(mm) Customer indicators and/or satisfaction;

(nn) New product invention or innovation;

(oo) Research and development expenses;

(pp) Attainment of research and development milestones;

(qq) Improvements in productivity;

(rr) Bookings;

(ss) Working-capital targets and changes in working capital;

(tt) Attainment of operating goals and employee metrics; and

(uu) Any other metric as determined by the Committee.

The Committee may provide for one or more equitable adjustments to the Performance Factors to preserve the Committee's original intent regarding the Performance Factors at the time of the initial award grant, such as but not limited to, adjustments in recognition of unusual or non-recurring items such as acquisition related activities or changes in applicable accounting rules. It is within the sole discretion of the Committee to make or not make any such equitable adjustments.

27.24. "***Performance Period***" means one or more periods of time, which may be of varying and overlapping durations, as the Committee may select, over which the attainment of one or more Performance Factors will be measured for the purpose of determining a Participant's right to, and the payment of, a Performance Award.

27.25. "***Performance Share***" means an Award as defined in Section 10 and granted under the Plan.

27.26. "***Permitted Transferee***" means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law (including adoptive relationships) of the Employee, any person sharing the Employee's household (other than a tenant or employee), a trust in which these persons (or the Employee) have more than 50% of the beneficial interest, a foundation in which these persons (or the Employee) control the management of assets, and any other entity in which these persons (or the Employee) own more than 50% of the voting interests.

27.27. *"**Performance Unit**"* means an Award as defined in Section 10 and granted under the Plan.

27.28. "***Plan***" means this Arcutis Biotherapeutics, Inc. 2022 Employment Inducement Incentive Plan.

27.29. "***Purchase Price***" means the price to be paid for Shares acquired under the Plan, other than Shares acquired upon exercise of an Option or SAR.

27.30. "***Restricted Stock Award***" means an Award as defined in Section 6 and granted under the Plan (or issued pursuant to the early exercise of an Option).

27.31. "***Restricted Stock Unit***" means an Award as defined in Section 9 and granted under the Plan.

27.32. "***SEC***" means the United States Securities and Exchange Commission.

27.33. "***Securities Act***" means the United States Securities Act of 1933, as amended.

27.34. "***Service***" means service as an Employee to the Company or a Subsidiary, subject to such further limitations as may be set forth in the Plan or the applicable Award Agreement. An Employee will not be deemed to have ceased to provide Service in the case of (a) sick leave, (b) military leave, or (c) any other leave of absence approved by the Company; provided, that such leave is for a period of not more than 90 days unless reemployment upon the expiration of such leave is guaranteed by contract or statute. Notwithstanding anything to the contrary, an Employee will not be deemed to have ceased to provide Service if a formal policy adopted from time to time by the Company and issued and promulgated to employees in writing provides otherwise. In the case of any Employee on an approved leave of absence or a reduction in hours worked (for illustrative purposes only, a change in schedule from that of full-time to part-time), the Committee may make such provisions respecting suspension or modification of vesting of the Award while on leave from the employ of the Company or a Subsidiary or during such change in working hours as it may deem appropriate, except that in no event may an Award be exercised after the expiration of the term set forth in the applicable Award Agreement. In the event of military or other protected leave, if required by applicable laws, vesting will continue for the longest period that vesting continues under any other statutory or Company approved leave of absence and, upon a Participant's returning from military leave, he or she will be given vesting credit with respect to Awards to the same extent as would have applied had the Participant continued to provide Service to the Company throughout the leave on the same terms as he or she was providing Service immediately prior to such leave. An Employee will have terminated employment as of the date he or she ceases to provide Service (regardless of whether the termination is in breach of local employment laws or is later found to be invalid) and employment will not be extended by any notice period or garden leave mandated by local law, *provided however*, a change in status from an Employee to a consultant or a Non-Employee Director (or vice versa) will not terminate a Participant's Service, unless determined by the Committee, in its discretion or to the extent set forth in the applicable Award Agreement. The Committee will have sole discretion to determine whether a Participant has ceased to provide Service and the effective date on which the Participant ceased to provide Service.

27.35. "***Shares***" means shares of the common stock of the Company.

27.36. "***Stock Appreciation Right***" means an Award as defined in Section 8 and granted under the Plan.

27.37. "***Stock Bonus***" means an Award granted pursuant to Section 7 of the Plan.

27.38. "***Subsidiary***" means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

27.39. "***Treasury Regulations***" means regulations promulgated by the United States Treasury Department.

27.40. "***Unvested Shares***" means Shares that have not yet vested or are subject to a right of repurchase in favor of the Company (or any successor thereto).

ARCUTIS BIOTHERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT INCENTIVE PLAN
GLOBAL NOTICE OF STOCK OPTION GRANT

Unless otherwise defined herein, the terms defined in the Arcutis Biotherapeutics, Inc. (the "***Company***") 2022 Employment Inducement Incentive Plan (the "***Plan***") will have the same meanings in this Global Notice of Stock Option Grant and the electronic representation of this Global Notice of Stock Option Grant established and maintained by the Company or a third party designated by the Company (this "***Notice***").

Name:
Address:

You ("***Participant***") have been granted an option to purchase shares of common stock of the Company (the "***Option***") under the Plan subject to the terms and conditions of the Plan, this Notice and the attached Global Stock Option Award Agreement (the "***Option Agreement***"), including any applicable country-specific provisions in the appendix attached hereto (the "***Appendix***"), which constitutes part of the Option Agreement.

Grant Number:

Date of Grant:

Vesting Commencement Date:

Exercise Price per Share:

Total Number of Shares:

Type of Option: Non-Qualified Stock Option

Expiration Date: _____ __, 20__; This Option expires earlier if Participant's Service terminates earlier, as described in the Option Agreement.

Vesting Schedule: Subject to the limitations set forth in this Notice, the Plan and the Option Agreement, the Option will vest in accordance with the following schedule: [insert applicable vesting schedule, which may be time-based, performance-based or a both]

By accepting (whether in writing, electronically or otherwise) the Option, Participant acknowledges and agrees to the following:

1) Participant understands that Participant's Service with the Company or a Subsidiary is for an unspecified duration, can be terminated at any time (*i.e.*, is "at-will"), except where otherwise prohibited by applicable law, and that nothing in this Notice, the Option Agreement or the Plan changes the nature of that relationship. Participant acknowledges that the vesting of the Option pursuant to this Notice is subject to Participant's continuing Service. To the extent permitted by applicable law, Participant agrees and acknowledges that the Vesting Schedule may change prospectively in the event that Participant's Service status changes between full- and part-time and/or in the event Participant is on a leave of absence, in accordance with Company policies relating to work schedules and vesting of Awards or as determined by the Committee to the extent permitted by applicable law. Furthermore, the period during which Participant may exercise the Option after termination of Service, if any, will commence on the Termination Date (as defined in the Option Agreement).

2) This grant is made under and governed by the Plan, the Option Agreement and this Notice, and this Notice is subject to the terms and conditions of the Option Agreement and the Plan, both of which are incorporated herein by reference. Participant has read the Notice, the Option Agreement and the Plan.

3) Participant has read the Company's Insider Trading Policy, and agrees to comply with such policy, as it may be amended from time to time, whenever Participant acquires or disposes of the Company's securities.

4) By accepting the Option, Participant consents to electronic delivery and participation as set forth in the Option Agreement.

ARCUTIS BIOTHERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT INCENTIVE PLAN
GLOBAL STOCK OPTION AWARD AGREEMENT

Unless otherwise defined in this Global Stock Option Award Agreement (this "***Option Agreement***"), any capitalized terms used herein will have the meaning ascribed to them in the Arcutis Biotherapeutics, Inc. 2022 Employment Inducement Incentive Plan (the "***Plan***").

Participant has been granted an option to purchase Shares (the "***Option***") of Arcutis Biotherapeutics, Inc. (the "***Company***"), subject to the terms, restrictions and conditions of the Plan, the Global Notice of Stock Option Grant (the "***Notice***") and this Option Agreement, including any applicable country-specific provisions in the appendix attached hereto (the "***Appendix***"), which constitutes part of this Option Agreement.

1. Vesting Rights. Subject to the applicable provisions of the Plan and this Option Agreement, this Option may be exercised, in whole or in part, in accordance with the Vesting Schedule set forth in the Notice. Participant acknowledges that the vesting of the Option pursuant to this Notice and Agreement is subject to Participant's continuing Service.

2. Grant of Option. Participant has been granted an Option for the number of Shares set forth in the Notice at the exercise price per Share in U.S. Dollars set forth in the Notice (the "***Exercise Price***"). In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of this Option Agreement, the terms and conditions of the Plan shall prevail. This Option it shall be treated as a Nonqualified Stock Option ("***NSO***").

3. Termination Period.

(a) General Rule. If Participant's Service terminates for any reason except death or Disability, and other than for Cause, then this Option will expire at the close of business at Company headquarters on the date three (3) months after Participant's Termination Date (as defined below) (or such shorter time period not less than thirty (30) days or longer time period as may be determined by the Committee). The Company determines when Participant's Service terminates for all purposes under this Option Agreement.

(b) Death; Disability. If Participant dies before Participant's Service terminates (or Participant dies within three months of Participant's termination of Service other than for Cause), then this Option will expire at the close of business at Company headquarters on the date twelve (12) months after the date of death (or such shorter time period not less than six (6) months or longer time period as may be determined by the Committee, subject to the expiration details in Section 7). If Participant's Service terminates because of Participant's Disability, then this Option will expire at the close of business at Company headquarters on the date twelve (12) months after Participant's Termination Date (or such shorter time period not less than six (6) months or longer time period as may be determined by the Committee, subject to the expiration details in Section 7).

(c) Cause. Unless otherwise determined by the Committee, the Option (whether or not vested) will terminate immediately upon the Participant's cessation of Services if the Company reasonably determines in good faith that such cessation of Services has resulted in connection with an act or failure to act constituting Cause (or the Participant's Services could have been terminated for Cause (without regard to the lapsing of any required notice or cure periods in connection therewith) at the time the Participant terminated Services).

(d) No Notification of Exercise Periods. Participant is responsible for keeping track of these exercise periods following Participant's termination of Service for any reason. The Company will not provide further notice of such periods. In no event shall this Option be exercised later than the Expiration Date set forth in the Notice.

(e) Termination. For purposes of this Option, Participant's Service will be considered terminated (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any) as of the date Participant is no longer actively providing services to the Company or one of its Subsidiaries (*i.e.*, Participant's period of Service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any) (the "***Termination Date***"). Unless otherwise provided in this Option Agreement or determined by the Company, Participant's right to vest in the Option under the Plan, if any, will terminate as of the Termination Date and Participant's right to exercise the Option after termination of Service, if any, will be measured from the Termination Date.

In case of any dispute as to whether and when a termination of Service has occurred, the Committee will have sole discretion to determine whether such termination of Service has occurred and the effective date of such termination (including whether Participant may still be considered to be actively providing Services while on a leave of absence).

If Participant does not exercise this Option within the termination period set forth in the Notice or the termination periods set forth above, the Option shall terminate in its entirety. In no event, may any Option be exercised after the Expiration Date of the Option as set forth in the Notice.

4. Exercise of Option.

(a) Right to Exercise. This Option is exercisable during its term in accordance with the Vesting Schedule set forth in the Notice and the applicable provisions of the Plan and this Option Agreement. In the event of Participant's death, Disability, termination for Cause or other cessation of Service, the exercisability of the Option is governed by the applicable provisions of the Plan, the Notice and this Option Agreement. This Option may not be exercised for a fraction of a Share.

(b) Method of Exercise. This Option is exercisable by delivery of an exercise notice in a form specified by the Company (the "***Exercise Notice***"), which will state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the "***Exercised Shares***"), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice will be delivered in person, by mail, via electronic mail or facsimile or by other authorized method to the Secretary of the Company or other person designated by the Company. The Exercise Notice will be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares together with any applicable Tax-Related Items (as defined in Section 8 below). This Option will be deemed to be exercised upon receipt by the Company of such fully executed Exercise Notice accompanied by such aggregate Exercise Price and payment of any applicable Tax-Related Items (as defined below). No Shares will be issued pursuant to the exercise of this Option unless such issuance and exercise complies with all relevant provisions of law and the requirements of any stock exchange or quotation service upon which the Shares are then listed and any exchange control registrations. Assuming such compliance, for United States income tax purposes the Exercised Shares will be considered transferred to Participant on the date the Option is exercised with respect to such Exercised Shares.

(c) Exercise by Another. If another person wants to exercise this Option after it has been transferred to him or her in compliance with this Option Agreement, that person must prove to the Company's satisfaction that he or she is entitled to exercise this Option. That person must also complete the proper Exercise Notice form (as described above) and pay the Exercise Price (as described below) and any applicable Tax-Related Items (as described below).

5. Method of Payment. Payment of the aggregate Exercise Price, and any Tax-Related Items withholding, will be by any of the following, or a combination thereof, at the election of Participant:

(a) Participant's personal check (representing readily available funds), wire transfer, or a cashier's check;

(b) if permitted by the Committee, certificates for shares of Company stock that Participant owns, along with any forms needed to effect a transfer of those shares to the Company; the value of the shares, determined as of the effective date of the Option exercise, will be applied to the Exercise Price. Instead of surrendering shares of Company stock, Participant may attest to the ownership of those shares on a form provided by the Company and have the same number of shares subtracted from the Option shares issued to Participant. However, Participant may not surrender, or attest to the ownership of, shares of Company stock in payment of the Exercise Price of Participant's Option if Participant's action would cause the Company to recognize compensation expense (or additional compensation expense) with respect to this Option for financial reporting purposes;

(c) cashless exercise through irrevocable directions to a securities broker approved by the Company to sell all or part of the Shares covered by this Option and to deliver to the Company from the sale proceeds an amount sufficient to pay the Exercise Price and any applicable Tax-Related Items withholding. The balance of the sale proceeds, if any, will be delivered to Participant unless otherwise provided in this Option Agreement. The directions must be given by signing a special notice of exercise form provided by the Company; or

(d) other method authorized by the Company;

provided, however, that the Company may restrict the available methods of payment due to facilitate compliance with applicable law or administration of the Plan. In particular, if Participant is located outside the United States,

Participant should review the applicable provisions of the Appendix for any such restrictions that may currently apply.

6. Non-Transferability of Option. This Option may not be sold, assigned, transferred, pledged, hypothecated, or otherwise disposed of other than by will or by the laws of descent or distribution or court order and may be exercised during the lifetime of Participant only by Participant or unless otherwise permitted by the Committee on a case-by-case basis. The terms of the Plan and this Option Agreement will be binding upon the executors, administrators, heirs, successors and assigns of Participant.

7. Term of Option. This Option will in any event expire on the expiration date set forth in the Notice, which date is 10 years after the Date of Grant.

8. Taxes.

(a) Responsibility for Taxes. Participant acknowledges that, to the extent permitted by applicable law, regardless of any action taken by the Company or a Subsidiary employing or retaining Participant (the "***Employer***"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax related items related to Participant's participation in the Plan and legally applicable to Participant ("***Tax-Related Items***") is and remains Participant's responsibility and may exceed the amount actually withheld by the Company or the Employer, if any. Participant further acknowledges that the Company and/or the Employer (i) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of this Option, including, but not limited to, the grant, vesting or exercise of this Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of this Option to reduce or eliminate Participant's liability for Tax-Related Items or achieve any particular tax result. Further, if Participant is subject to Tax-Related Items in more than one jurisdiction, Participant acknowledges that the Company and/or the Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction. *PARTICIPANT SHOULD CONSULT A TAX ADVISER APPROPRIATELY QUALIFIED IN EACH OF THE JURISDICTIONS, INCLUDING COUNTRY OR COUNTRIES IN WHICH PARTICIPANT RESIDES OR IS SUBJECT TO TAXATION BEFORE EXERCISING THE OPTION OR DISPOSING OF THE SHARES.*

(b) Withholding. Prior to any relevant taxable or tax withholding event, as applicable, to the extent permitted by applicable law Participant agrees to make arrangements satisfactory to the Company and/or the Employer to fulfill all Tax-Related Items. In this regard, Participant authorizes the Company and/or the Employer, or their respective agents, at their discretion, to satisfy any withholding obligations for Tax-Related Items by one or a combination of the following:

(i) withholding from Participant's wages or other cash compensation paid to Participant by the Company and/or the Employer or any Subsidiary; or

(ii) withholding from proceeds of the sale of Shares acquired at exercise of this Option either through a voluntary sale or through a mandatory sale arranged by the Company (on Participant's behalf pursuant to this authorization and without further consent); or

(iii) withholding Shares to be issued upon exercise of the Option, provided the Company only withholds the number of Shares necessary to satisfy no more than the maximum statutory withholding amounts;

(iv) Participant's payment of a cash amount (including by check representing readily available funds or a wire transfer); or

(v) any other arrangement approved by the Committee and permitted under applicable law;

all under such rules as may be established by the Committee and in compliance with the Company's Insider Trading Policy and 10b5-1 Trading Plan Policy, if applicable; provided however, that if Participant is a Section 16 officer of the Company under the Exchange Act, then the Committee (as constituted in accordance with Rule 16b-3 under the Exchange Act) shall establish the method of withholding from alternatives (i)-(v) above, and the Committee shall establish the method prior to the Tax-Related Items withholding event.

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable statutory withholding rates or other applicable withholding rates, including up to the

maximum permissible statutory rate for Participant's tax jurisdiction(s) in which case Participant will have no entitlement to the equivalent amount in Shares and may receive a refund of any over-withheld amount in cash in accordance with applicable law. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, Participant is deemed to have been issued the full number of Exercised Shares; notwithstanding that a number of the Shares are held back solely for the purpose of satisfying the withholding obligation for Tax-Related Items.

Finally, Participant agrees to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold or account for as a result of Participant's participation in the Plan that cannot be satisfied by the means previously described. The Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares, if Participant fails to comply with Participant's obligations in connection with the Tax-Related Items.

9. Nature of Grant. By accepting the Option, Participant acknowledges, understands and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the Option is exceptional, voluntary and occasional and does not create any contractual or other right to receive future grants of options, or benefits in lieu of options, even if options have been granted in the past;

(c) all decisions with respect to future options or other grants, if any, will be at the sole discretion of the Company;

(d) Participant is voluntarily participating in the Plan;

(e) the Option and Participant's participation in the Plan will not create a right to employment or be interpreted as forming or amending an employment or service contract with the Company, the Employer or any Subsidiary, and shall not interfere with the ability of the Company, the Employer or any Subsidiary, as applicable, to terminate Participant's employment or service relationship (if any);

(f) the Option and the Shares subject to the Option, and the income from and value of same, are not intended to replace any pension rights or compensation;

(g) the Option and the Shares subject to the Option, and the income from and value of same, are not part of normal or expected compensation for any purpose, including, but not limited to, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(h) unless otherwise agreed with the Company, the Option and the Shares subject to the Option, and the income from and value of same, are not granted as consideration for, or in connection with, the service Participant may provide as a director of a Subsidiary;

(i) the future value of the Shares underlying the Option is unknown, indeterminable and cannot be predicted with certainty; if the underlying Shares do not increase in value, the Option will have no value; if Participant exercises the Option and acquires Shares, the value of such Shares may increase or decrease, even below the Exercise Price;

(j) no claim or entitlement to compensation or damages will arise from forfeiture of the Option resulting from Participant's termination of Service (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any); and

(k) neither the Company, the Employer nor any Subsidiary will be liable for any foreign exchange rate fluctuation between Participant's local currency and the United States Dollar that may affect the value of the Option or of any amounts due to Participant pursuant to the exercise of the Option or the subsequent sale of any Shares acquired upon exercise.

10. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's participation in the Plan, or Participant's acquisition or sale of the underlying Shares. Participant acknowledges, understands and agrees that he or she should consult with his or her own personal tax, legal and financial advisors regarding his or her participation in the Plan before taking any action related to the Plan.

11. ***Data Privacy. Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of Participant's personal data as described in this Option Agreement and any other Option grant materials by and among, as applicable, the Employer, the Company and any Subsidiary for the exclusive purpose of implementing, administering and managing Participant's participation in the Plan.***

Participant understands that the Company and the Employer may hold certain personal information about Participant, including, but not limited to, Participant's name, home address, email address and telephone number, date of birth, social insurance number, passport number or other identification number (e.g., resident registration number), salary, nationality, job title, any shares of stock or directorships held in the Company, details of all Options or any other entitlement to shares of stock awarded, canceled, exercised, vested, unvested or outstanding in Participant's favor ("Data"), for the exclusive purpose of implementing, administering and managing the Plan.

Participant understands that Data will be transferred to the Company's designated third-party broker, or other third party ("Online Administrator") and its affiliated companies or such other stock plan service provider as may be designated by the Company from time to time, which is assisting the Company with the implementation, administration and management of the Plan. Participant understands that the recipients of Data may be located in the United States or elsewhere, and that the recipients' country may have different data privacy laws and protections than Participant's country. Participant understands that if he or she resides outside the United States, he or she may request a list with the names and addresses of any potential recipients of Data by contacting his or her local human resources representative. Participant authorizes the Company, the Company's designated third-party broker, or such other stock plan service provider as may be designated by the Company from time to time, and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer Data, in electronic or other form, for the sole purpose of implementing, administering and managing his or her participation in the Plan. Participant understands that Data will be held only as long as is necessary to implement, administer and manage Participant's participation in the Plan. Participant understands if he or she resides outside the United States, he or she may, at any time, view Data, request information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting his or her local human resources representative. Further, Participant understands that he or she is providing the consents herein on a purely voluntary basis. If Participant does not consent, or if Participant later seeks to revoke his or her consent, his or her employment status or service with the Employer will not be affected; the only consequence of refusing or withdrawing Participant's consent is that the Company would not be able to grant Options or other equity awards to Participant or administer or maintain such awards. Therefore, Participant understands that refusing or withdrawing his or her consent may affect Participant's ability to participate in the Plan. For more information on the consequences of Participant's refusal to consent or withdrawal of consent, Participant understands that he or she may contact his or her local human resources representative.

Finally, upon request of the Company or the Employer, Participant agrees to provide an executed data privacy consent form (or any other agreements or consents) that the Company or the Employer may deem necessary to obtain from Participant for the purpose of administering Participant's participation in the Plan in compliance with the data privacy laws in Participant's country, either now or in the future. Participant understands and agrees that Participant will not be able to participate in the Plan if Participant fails to provide any such consent or agreement requested by the Company and/or the Employer.

12. Language. Participant acknowledges that he or she is sufficiently proficient in English to understand the terms and conditions of this Option Agreement. Furthermore, if Participant has received this Option Agreement, or any other document related to the Option and/or the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

13. Appendix. Notwithstanding any provisions in this Option Agreement, the Option will be subject to any special terms and conditions set forth in any appendix to this Option Agreement for Participant's country. Moreover, if Participant relocates to one of the countries included in the Appendix, the special terms and conditions for such country will apply to Participant, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Option Agreement.

14. Imposition of Other Requirements. The Company reserves the right to impose other requirements on Participant's participation in the Plan, on the Option and on any Shares purchased upon exercise of the Option, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require Participant to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

15. Acknowledgement. The Company and Participant agree that the Option is granted under and governed by the Notice, this Option Agreement and the provisions of the Plan (incorporated herein by reference). Participant: (a) acknowledges receipt of a copy of the Plan and the Plan prospectus, (b) represents that Participant has carefully read and is familiar with their provisions, and (c) hereby accepts the Option subject to all of the terms and conditions set forth herein and those set forth in the Plan and the Notice.

16. Entire Agreement; Enforcement of Rights. This Option Agreement, the Plan and the Notice constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning the purchase of the Shares hereunder are superseded. No adverse modification of, or adverse amendment to, this Option Agreement, nor any waiver of any rights under this Option Agreement, will be effective unless in writing and signed by the parties to this Option Agreement (which writing and signing may be electronic). The failure by either party to enforce any rights under this Option Agreement will not be construed as a waiver of any rights of such party.

17. Compliance with Laws and Regulations. The issuance of Shares will be subject to and conditioned upon compliance by the Company and Participant with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Shares may be listed or quoted at the time of such issuance or transfer. Participant understands that the Company is under no obligation to register or qualify the Shares with any state, federal or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the Shares. Further, Participant agrees that the Company shall have unilateral authority to amend the Plan and this Option Agreement without Participant's consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares. Finally, the Shares issued pursuant to this Option Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

18. Severability. If one or more provisions of this Option Agreement are held to be unenforceable under applicable law, then such provision will be enforced to the maximum extent possible given the intent of the parties hereto. If such clause or provision cannot be so enforced, then (a) such provision will be excluded from this Option Agreement, (b) the balance of this Option Agreement will be interpreted as if such provision were so excluded and (c) the balance of this Option Agreement will be enforceable in accordance with its terms.

19. Governing Law and Venue. This Option Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto will be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to such state's conflict of laws rules.

Any and all disputes relating to, concerning or arising from this Option Agreement, or relating to, concerning or arising from the relationship between the parties evidenced by the Plan or this Option Agreement, will be brought and heard exclusively in the United States District Court for the District of Southern California or the Superior Court of California, County of Los Angeles. Each of the parties hereby represents and agrees that such party is subject to the personal jurisdiction of said courts; hereby irrevocably consents to the jurisdiction of such courts in any legal or equitable proceedings related to, concerning or arising from such dispute, and waives, to the fullest extent permitted by law, any objection which such party may now or hereafter have that the laying of the venue of any legal or equitable proceedings related to, concerning or arising from such dispute which is brought in such courts is improper or that such proceedings have been brought in an inconvenient forum.

20. No Rights as Employee. Nothing in this Option Agreement will affect in any manner whatsoever any right or power of the Company, or a Subsidiary, to terminate Participant's Service, for any reason, with or without Cause.

21. Consent to Electronic Delivery of All Plan Documents and Disclosures. By Participant's acceptance of the Notice (whether in writing or electronically), Participant and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan, the Notice and this Option Agreement. Participant has reviewed the Plan, the Notice and this Option Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Notice and Agreement, and fully understands all provisions of the Plan, the Notice and this Option Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice and this Option Agreement. Participant further agrees to notify the Company upon any change in the residence address. By acceptance of this Option, Participant agrees to participate in the Plan through an on-line or electronic system established and

maintained by the Company or a third party designated by the Company and consents to the electronic delivery of the Notice, this Option Agreement, the Plan, account statements, Plan prospectuses required by the SEC, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its security holders (including, without limitation, annual reports and proxy statements) or other communications or information related to the Option and current or future participation in the Plan. Electronic delivery may include the delivery of a link to the Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. Participant acknowledges that

Participant may receive from the Company a paper copy of any documents delivered electronically at no cost if Participant contacts the Company by telephone, through a postal service or electronic mail to Stock Administration. Participant further acknowledges that Participant will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, Participant understands that Participant must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. Also, Participant understands that Participant's consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if Participant has provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail to Stock Administration.

22. Insider Trading Restrictions/Market Abuse Laws. Participant acknowledges that, depending on Participant's country of residence, the broker's country, or the country in which the Shares are listed, Participant may be subject to insider trading restrictions and/or market abuse laws in applicable jurisdictions, which may affect Participant's ability to directly or indirectly, accept, acquire, sell or attempt to sell or otherwise dispose of Shares, or rights to Shares (*e.g.,* Options), or rights linked to the value of Shares, during such times as Participant is considered to have "inside information" regarding the Company (as defined by the laws or regulations in the applicable jurisdiction). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders Participant placed before possessing the inside information. Furthermore, Participant may be prohibited from (i) disclosing the inside information to any third party, including fellow employees (other than on a "need to know" basis) and (ii) "tipping" third parties or causing them to otherwise buy or sell securities. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. Participant acknowledges that it is Participant's responsibility to comply with any applicable restrictions and understands that Participant should consult his or her personal legal advisor on such matters. In addition, Participant acknowledges that he or she read the Company's Insider Trading Policy, and agrees to comply with such policy, as it may be amended from time to time, whenever Participant acquires or disposes of the Company's securities.

23. Foreign Asset/Account, Exchange Control and Tax Reporting. Participant may be subject to foreign asset/account, exchange control and/or tax reporting requirements as a result of the acquisition, holding and/or transfer of Shares or cash resulting from his or her participation in the Plan. Participant may be required to report such accounts, assets, the balances therein, the value thereof and/or the transactions related thereto to the applicable authorities in Participant's country and/or repatriate funds received in connection with the Plan within certain time limits or according to specified procedures. Participant acknowledges that he or she is responsible for ensuring compliance with any applicable foreign asset/account, exchange control and tax reporting requirements and should consult his or her personal legal and tax advisors on such matters.

24. Award Subject to Company Clawback or Recoupment. The Option shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of Participant's employment or other Service that is applicable to Participant. In addition to any other remedies available under such policy, applicable law may require the cancellation of Participant's Option (whether vested or unvested) and the recoupment of any gains realized with respect to Participant's Option.

BY ACCEPTING THIS OPTION, PARTICIPANT AGREES TO ALL OF THE TERMS AND CONDITIONS DESCRIBED ABOVE AND IN THE PLAN.

APPENDIX

ARCUTIS BIOTHERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT INCENTIVE PLAN
GLOBAL STOCK OPTION AWARD AGREEMENT

COUNTRY SPECIFIC PROVISIONS FOR EMPLOYEES OUTSIDE THE U.S.

Not applicable

ARCUTIS BIOTHERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT INCENTIVE PLAN
GLOBAL NOTICE OF RESTRICTED STOCK UNIT AWARD

Unless otherwise defined herein, the terms defined in the Arcutis Biotherapeutics, Inc. (the "***Company***") 2022 Employment Inducement Incentive Plan (the "***Plan***") will have the same meanings in this Global Notice of Restricted Stock Unit Award and the electronic representation of this Global Notice of Restricted Stock Unit Award established and maintained by the Company or a third party designated by the Company (this "***Notice***").

Name:
Address:

You ("***Participant***") have been granted an award of Restricted Stock Units ("***RSUs***") under the Plan subject to the terms and conditions of the Plan, this Notice and the attached Global Restricted Stock Unit Award Agreement (the "***Agreement***"), including any applicable country-specific provisions in the appendix attached hereto (the "***Appendix***"), which constitutes part of the Agreement.

Grant Number:

Number of RSUs:

Date of Grant:

Vesting Commencement Date:

Expiration Date: The earlier to occur of: (a) the date on which settlement of all RSUs granted hereunder occurs and (b) the tenth anniversary of the Date of Grant. This RSU expires earlier if Participant's Service terminates earlier, as described in the Agreement.

Vesting Schedule: Subject to the limitations set forth in this Notice, the Plan and the Agreement, the RSUs will vest in accordance with the following schedule: [insert applicable vesting schedule]

By accepting (whether in writing, electronically or otherwise) the RSUs, Participant acknowledges and agrees to the following:

1) Participant understands that Participant's Service with the Company or a Subsidiary is for an unspecified duration, can be terminated at any time (*i.e.*, is "at-will"), except where otherwise prohibited by applicable law, and that nothing in this Notice, the Agreement or the Plan changes the nature of that relationship. Participant acknowledges that the vesting of the RSUs pursuant to this Notice is subject to Participant's continuing Service. To the extent permitted by applicable law, Participant agrees and acknowledges that the Vesting Schedule may change prospectively in the event that Participant's Service status changes between full- and part-time and/or in the event Participant is on a leave of absence, in accordance with Company policies relating to work schedules and vesting of Awards or as determined by the Committee.

2) This grant is made under and governed by the Plan, the Agreement and this Notice, and this Notice is subject to the terms and conditions of the Agreement and the Plan, both of which are incorporated herein by reference. Participant has read the Notice, the Agreement and the Plan.

3) Participant has read the Company's Insider Trading Policy, and agrees to comply with such policy, as it may be amended from time to time, whenever Participant acquires or disposes of the Company's securities.

4) By accepting the RSUs, Participant consents to electronic delivery and participation as set forth in the Agreement.

5) By accepting the RSUs, to unless Participant has a valid 10b5-1 plan in place directing the sale of Shares to cover the Tax-Related Items (as defined in the Agreement), Participant agrees to the 10b5-1 Arrangement described in Section 6 of the Agreement.

ARCUTIS BIOTHERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT INCENTIVE PLAN
GLOBAL RESTRICTED STOCK UNIT AWARD AGREEMENT

Unless otherwise defined in this Global Restricted Stock Unit Award Agreement (this "***Agreement***"), any capitalized terms used herein will have the same meaning ascribed to them in the Arcutis Biotherapeutics, Inc. 2022 Employment Inducement Incentive Plan (the "***Plan***").

Participant has been granted Restricted Stock Units ("***RSUs***") subject to the terms, restrictions and conditions of the Plan, the Global Notice of Restricted Stock Unit Award (the "***Notice***") and this Agreement, including any applicable country-specific provisions in the appendix attached hereto (the "***Appendix***"), which constitutes part of this Agreement. In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of the Notice or this Agreement, the terms and conditions of the Plan shall prevail.

1. Settlement. Settlement of RSUs will be made within 30 days following the applicable date of vesting under the Vesting Schedule set forth in the Notice. Settlement of RSUs will be in Shares. No fractional RSUs or rights for fractional Shares shall be created pursuant to this Agreement.

2. No Stockholder Rights. Unless and until such time as Shares are issued in settlement of vested RSUs, Participant will have no ownership of the Shares allocated to the RSUs and will have no rights to dividends or to vote such Shares.

3. Dividend Equivalents. Dividends, if any (whether in cash or Shares), will not be credited to Participant.

4. Non-Transferability of RSUs. The RSUs and any interest therein will not be sold, assigned, transferred, pledged, hypothecated, or otherwise disposed of in any manner other than by will or by the laws of descent or distribution or court order or unless otherwise permitted by the Committee on a case-by-case basis.

5. Termination. If Participant's Service terminates for any reason, all unvested RSUs will be forfeited to the Company forthwith, and all rights of Participant to such RSUs will immediately terminate without payment of any consideration to Participant. Participant's Service will be considered terminated (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any) as of the date Participant is no longer actively providing services and Participant's Service will not be extended by any notice period (e.g., Participant's Service would not include a period of "garden leave" or similar period mandated under employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any). Participant acknowledges and agrees that the Vesting Schedule may change prospectively in the event Participant's service status changes between full- and part-time and/or in the event Participant is on a leave of absence, in accordance with Company policies relating to work schedules and vesting of awards or as determined by the Committee. In case of any dispute as to whether and when a termination of Service has occurred, the Committee will have sole discretion to determine whether such termination of Service has occurred and the effective date of such termination (including whether Participant may still be considered to be actively providing Services while on a leave of absence).

6. Taxes.

(a) Responsibility for Taxes. Participant acknowledges that, to the extent permitted by applicable law, regardless of any action taken by the Company or a Subsidiary employing or retaining Participant (the "***Employer***"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to Participant's participation in the Plan and legally applicable to Participant ("***Tax-Related Items***") is and remains Participant's responsibility and may exceed the amount actually withheld by the Company or the Employer, if any. Participant further acknowledges that the Company and/or the Employer (i) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the RSUs, including, but not limited to, the grant, vesting or settlement of the RSUs and the subsequent sale of Shares acquired pursuant to such settlement and the receipt of any dividends, and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the RSUs to reduce or eliminate Participant's liability for Tax-Related Items or achieve any particular tax result. Further, if Participant is subject to Tax-Related Items in more than one jurisdiction, Participant acknowledges that the Company and/or the Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction. *PARTICIPANT SHOULD CONSULT A TAX ADVISER APPROPRIATELY QUALIFIED IN EACH OF THE JURISDICTIONS, INCLUDING COUNTRY OR COUNTRIES IN WHICH PARTICIPANT RESIDES OR IS SUBJECT TO TAXATION.*

(b) Withholding. Prior to any relevant taxable or tax withholding event, as applicable, to the extent permitted by applicable law, Participant agrees to make arrangements satisfactory to the Company and/or the Employer to fulfill all Tax-Related Items. In this regard, Participant authorizes the Company and/or the Employer, or their respective agents, at their discretion as follows:

(i) Notwithstanding anything to the contrary contained in the Plan or this Section 6, unless Participant has a valid 10b5-1 plan in place directing the sale of Shares to cover the Tax-Related Items, the Tax-Related Items shall automatically, and without further action by Participant, be satisfied by having the Company withhold taxes from the proceeds of the sale of the Shares through a mandatory sale arranged by the Company on Participant's behalf. In the event Participant's Tax-Related Items will be satisfied under this Section 6(b), then the Company shall instruct any brokerage firm determined acceptable to the Company for such purpose to sell on Participant's behalf a whole number of shares from those Shares issuable to Participant upon settlement of the RSUs as is required to generate cash proceeds sufficient to satisfy Participant's Tax-Related Items (with such Tax-Related Items to be calculated based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes as of the date of delivery). Participant acknowledges that the instruction to the broker to sell Shares pursuant to this Section 6(b) is intended to comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act and to be interpreted to comply with the requirements of Rule 10b5-1(c)(1) under the Exchange Act (the "***10b5-1 Arrangement***"). This 10b5-1 Arrangement is being adopted to permit the Company to sell (on Participant's behalf) a number of Shares issuable to Participant upon the settlement of the RSUs sufficient to pay the Tax-Related Items that arises as a result of the vesting or settlement of the RSUs. Participant hereby acknowledges that the broker is under no obligation to arrange for such sale at any particular price. Participant hereby appoints the Company as Participant's agent and attorney-in-fact to instruct the broker with respect to the number of Shares to be sold under this 10b5-1 Arrangement. Participant acknowledges that it may not be possible to sell Shares during the term of this 10b5-1 Arrangement due to (A) a legal or contractual restriction applicable to Participant or to the broker, (B) a market disruption, (C) rules governing order execution priority on the stock exchange on which the Shares are traded, (D) a sale effected pursuant to this 10b5-1 Arrangement that fails to comply (or in the reasonable opinion of the broker's counsel is likely not to comply) with Rule 144 under the Securities Act or would result in a short-swing profit under Section 16 of the Exchange Act, or (E) the Company's determination that sales may not be effected under this 10b5-1 Arrangement.

(ii) This 10b5-1 Arrangement shall terminate as to the RSUs on the earliest of: (A) completion of the final sale of Shares withheld pursuant to this Section 6(b) following the final vesting date attributable to the RSUs; (B) termination of the RSUs; (C) the date of Participant's death; or (D) as soon as practicable after (but in no event later than the end of the next business day following) the announcement of (1) a tender or exchange offer for shares of Common Stock by the Company or any other person, or (2) a merger, acquisition, recapitalization or comparable transaction as a result of which Common Stock is to be exchanged or converted into shares of another company.

(iii) Participant represents that (A) Participant is not presently aware of any material nonpublic information about the Company or its securities; (B) Participant is entering into this Agreement and the 10b5-1 Arrangement in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 or any other provision of any federal, state or foreign securities laws or regulations; (C) Participant shall have full responsibility for compliance with (1) any reporting requirements under Section 13 or 16 of the Exchange Act, (2) the short-swing profit recovery provisions under Section 16 of the Exchange Act, and (3) any federal, state or foreign securities laws or regulations concerning trading while aware of material nonpublic information; and (D) Participant is aware that in order for this 10b5-1 Arrangement to constitute an instruction pursuant to Rule 10b5-1(c), Participant must not alter or deviate from the terms of the instruction in this Section 3.2(b) (whether by changing the amount, price, or timing of any purchase or sale hereunder), exercise any subsequent discretion over the terms hereof or enter into or alter a corresponding or hedging transaction with respect to the Common Stock to be sold pursuant to this instruction or any securities convertible into or exchangeable for such Common Stock.

(iv) Participant acknowledges that this 10b5-1 Arrangement is subject to the terms of any policy adopted now or hereafter by the Company governing the adoption of 10b5-1 plans. Participant's acceptance of the RSUs constitutes the Participant's instruction and authorization to the Company and any brokerage firm to complete the transactions described in this Section 6(b).

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable statutory withholding rates or other applicable withholding rates, including up to the maximum permissible statutory rate for Participant's tax jurisdiction(s) in which case Participant will have no

entitlement to the equivalent amount in Shares and may receive a refund of any over-withheld amount in cash in accordance with applicable law.

To the extent that the Tax-Related Items is not fully satisfied pursuant to Section 6(b) or Section 6(b) does not apply, the Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the RSUs (provided, however, that if Participant is subject to Section 16 of the Exchange Act at the time the tax withholding obligation arises, the prior approval of the Administrator shall be required for any election by the Company pursuant to this paragraph). If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, Participant is deemed to have been issued the full number of Shares subject to the vested RSUs, notwithstanding that a number of the Shares are held back solely for the purpose of satisfying the withholding obligation for Tax-Related Items. Finally, Participant agrees to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold or account for as a result of Participant's participation in the Plan that cannot be satisfied by the means previously described. The Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares, if Participant fails to comply with Participant's obligations in connection with the Tax-Related Items.

7. Nature of Grant. By accepting the RSUs, Participant acknowledges, understands and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the RSUs is exceptional, voluntary and occasional and does not create any contractual or other right to receive future grants of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past;

(c) all decisions with respect to future RSUs or other grants, if any, will be at the sole discretion of the Company;

(d) Participant is voluntarily participating in the Plan;

(e) the RSUs and Participant's participation in the Plan will not create a right to employment or be interpreted as forming or amending an employment or service contract with the Company, the Employer or any Subsidiary and shall not interfere with the ability of the Company, the Employer or any Subsidiary, as applicable, to terminate Participant's employment or service relationship (if any);

(f) the RSUs and the Shares subject to the RSUs, and the income from and value of same, are not intended to replace any pension rights or compensation;

(g) the RSUs and the Shares subject to the RSUs, and the income from and value of same, are not part of normal or expected compensation for any purpose, including, but not limited to, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(h) unless otherwise agreed with the Company, the RSUs and the Shares subject to the RSUs, and the income from and value of same, are not granted as consideration for, or in connection with, the service Participant may provide as a director of a Subsidiary;

(i) the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

(j) no claim or entitlement to compensation or damages will arise from forfeiture of the RSUs resulting from Participant's termination of Service (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any); and

(k) neither the Company, the Employer nor any Subsidiary will be liable for any foreign exchange rate fluctuation between Participant's local currency and the United States Dollar that may affect the value of the RSUs or of any amounts due to Participant pursuant to the settlement of the RSUs or the subsequent sale of any Shares acquired upon settlement.

8. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's participation in the Plan, or Participant's acquisition or sale of the underlying Shares. Participant acknowledges, understands and agrees he or she should consult with his or her own personal tax, legal and financial advisors regarding his or her participation in the Plan before taking any action related to the Plan.

9. Data Privacy. Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of Participant's personal data as described in this Agreement and any other RSU grant materials by and among, as applicable, the Employer, the Company and any Subsidiary for the exclusive purpose of implementing, administering and managing Participant's participation in the Plan.

Participant understands that the Company and the Employer may hold certain personal information about Participant, including, but not limited to, Participant's name, home address, email address and telephone number, date of birth, social insurance number, passport number or other identification number (e.g., resident registration number), salary, nationality, job title, any shares of stock or directorships held in the Company, details of all RSUs or any other entitlement to shares of stock awarded, canceled, exercised, vested, unvested or outstanding in Participant's favor ("Data"), for the exclusive purpose of implementing, administering and managing the Plan.

Participant understands that Data will be transferred to the Company's designated third-party broker, or other third party ("Online Administrator") and its affiliated companies or such other stock plan service provider as may be designated by the Company from time to time, which is assisting the Company with the implementation, administration and management of the Plan. Participant understands that the recipients of Data may be located in the United States or elsewhere, and that the recipients' country may have different data privacy laws and protections than Participant's country. Participant understands that if he or she resides outside the United States, he or she may request a list with the names and addresses of any potential recipients of Data by contacting his or her local human resources representative. Participant authorizes the Company, the Company's designated third-party broker, or such other stock plan service provider as may be designated by the Company from time to time, and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer Data, in electronic or other form, for the sole purpose of implementing, administering and managing his or her participation in the Plan. Participant understands that Data will be held only as long as is necessary to implement, administer and manage Participant's participation in the Plan. Participant understands if he or she resides outside the United States, he or she may, at any time, view Data, request information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting his or her local human resources representative. Further, Participant understands that he or she is providing the consents herein on a purely voluntary basis. If Participant does not consent, or if Participant later seeks to revoke his or her consent, his or her employment status or service with the Employer will not be affected; the only consequence of refusing or withdrawing Participant's consent is that the Company would not be able to grant RSUs or other equity awards to Participant or administer or maintain such awards. Therefore, Participant understands that refusing or withdrawing his or her consent may affect Participant's ability to participate in the Plan. For more information on the consequences of Participant's refusal to consent or withdrawal of consent, Participant understands that he or she may contact his or her local human resources representative.

Finally, upon request of the Company or the Employer, Participant agrees to provide an executed data privacy consent form (or any other agreements or consents) that the Company or the Employer may deem necessary to obtain from Participant for the purpose of administering Participant's participation in the Plan in compliance with the data privacy laws in Participant's country, either now or in the future. Participant understands and agrees that Participant will not be able to participate in the Plan if Participant fails to provide any such consent or agreement requested by the Company and/or the Employer.

10. Language. Participant acknowledges that he or she is sufficiently proficient in English to understand the terms and conditions of this Agreement. Furthermore, if Participant has received this Agreement or any other document related to the RSU and/or the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

11. Appendix. Notwithstanding any provisions in this Agreement, the RSUs will be subject to any special terms and conditions set forth in any appendix to this Agreement for Participant's country. Moreover, if Participant relocates to one of the countries included in the Appendix, the special terms and conditions for such country will apply to Participant, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

12. Imposition of Other Requirements. The Company reserves the right to impose other requirements on Participant's participation in the Plan, on the RSUs and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require Participant to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

13. Acknowledgement. The Company and Participant agree that the RSUs are granted under and governed by the Notice, this Agreement and the provisions of the Plan (incorporated herein by reference). Participant: (a) acknowledges receipt of a copy of the Plan and the Plan prospectus, (b) represents that Participant has carefully read and is familiar with their provisions, and (c) hereby accepts the RSUs subject to all of the terms and conditions set forth herein and those set forth in the Plan and the Notice.

14. Entire Agreement; Enforcement of Rights. This Agreement, the Plan and the Notice constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning the purchase of the Shares hereunder are superseded. No adverse modification of or adverse amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by the parties to this Agreement (which writing and signing may be electronic). The failure by either party to enforce any rights under this Agreement will not be construed as a waiver of any rights of such party.

15. Compliance with Laws and Regulations. The issuance of Shares will be subject to and conditioned upon compliance by the Company and Participant with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Shares may be listed or quoted at the time of such issuance or transfer. Participant understands that the Company is under no obligation to register or qualify the Shares with any state, federal or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the Shares. Further, Participant agrees that the Company shall have unilateral authority to amend the Plan and this RSU Agreement without Participant's consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares. Finally, the Shares issued pursuant to this RSU Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

16. Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, then such provision will be enforced to the maximum extent possible given the intent of the parties hereto. If such clause or provision cannot be so enforced, then (a) such provision will be excluded from this Agreement, (b) the balance of this Agreement will be interpreted as if such provision were so excluded and (c) the balance of this Agreement will be enforceable in accordance with its terms.

17. Governing Law and Venue. This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto will be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to such state's conflict of laws rules.

Any and all disputes relating to, concerning or arising from this Agreement, or relating to, concerning or arising from the relationship between the parties evidenced by the Plan or this Agreement, will be brought and heard exclusively in the United States District Court for the District of Southern California or the Superior Court of California, County of Los Angeles. Each of the parties hereby represents and agrees that such party is subject to the personal jurisdiction of said courts; hereby irrevocably consents to the jurisdiction of such courts in any legal or equitable proceedings related to, concerning or arising from such dispute, and waives, to the fullest extent permitted by law, any objection which such party may now or hereafter have that the laying of the venue of any legal or equitable proceedings related to, concerning or arising from such dispute which is brought in such courts is improper or that such proceedings have been brought in an inconvenient forum.

18. No Rights as Employee. Nothing in this Agreement will affect in any manner whatsoever any right or power of the Company, or a Subsidiary, to terminate Participant's Service, for any reason, with or without Cause.

19. Consent to Electronic Delivery of All Plan Documents and Disclosures. By Participant's acceptance of the Notice (whether in writing or electronically), Participant and the Company agree that the RSUs are granted under and governed by the terms and conditions of the Plan, the Notice and this Agreement. Participant has reviewed the Plan, the Notice and this Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Notice and Agreement, and fully understands all provisions of the Plan, the Notice and this Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice and this Agreement. Participant further agrees to notify the Company upon any change in Participant's residence address. By acceptance of the RSUs, Participant agrees to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company and consents to the electronic delivery of the Notice, this Agreement, the

Plan, account statements, Plan prospectuses required by the SEC, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its security holders (including, without limitation, annual reports and proxy statements) or other communications or information related to the RSUs and current or future participation in the Plan. Electronic delivery may include the delivery of a link to the Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. Participant acknowledges that Participant may receive from the Company a paper copy of any documents delivered electronically at no cost if Participant contacts the Company by telephone, through a postal service or electronic mail to Stock Administration. Participant further acknowledges that Participant will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, Participant understands that Participant must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. Also, Participant understands that Participant's consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if Participant has provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail to Stock Administration.

20. Insider Trading Restrictions/Market Abuse Laws. Participant acknowledges that, depending on Participant's country of residence, the broker's country, or the country in which the Shares are listed, Participant may be subject to insider trading restrictions and/or market abuse laws in applicable jurisdictions, which may affect Participant's ability to directly or indirectly, accept, acquire, sell or attempt to sell or otherwise dispose of Shares, or rights to Shares (*e.g.*, RSUs), or rights linked to the value of Shares, during such times as Participant is considered to have "inside information" regarding the Company (as defined by the laws or regulations in the applicable jurisdiction). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders Participant placed before possessing the inside information. Furthermore, Participant may be prohibited from (i) disclosing the inside information to any third party, including fellow employees (other than on a "need to know" basis) and (ii) "tipping" third parties or causing them to otherwise buy or sell securities. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. Participant acknowledges that it is Participant's responsibility to comply with any applicable restrictions and understands that Participant should consult his or her personal legal advisor on such matters. In addition, Participant acknowledges that he or she read the Company's Insider Trading Policy, and agrees to comply with such policy, as it may be amended from time to time, whenever Participant acquires or disposes of the Company's securities.

21. Foreign Asset/Account, Exchange Control and Tax Reporting. Participant may be subject to foreign asset/account, exchange control and/or tax reporting requirements as a result of the acquisition, holding and/or transfer of Shares or cash resulting from his or her participation in the Plan. Participant may be required to report such accounts, assets, the balances therein, the value thereof and/or the transactions related thereto to the applicable authorities in Participant's country and/or repatriate funds received in connection with the Plan within certain time limits or according to specified procedures. Participant acknowledges that he or she is responsible for ensuring compliance with any applicable foreign asset/account, exchange control and tax reporting requirements and should consult his or her personal legal and tax advisors on such matters.

22. Code Section 409A. For purposes of this Agreement, a termination of employment will be determined consistent with the rules relating to a "separation from service" as defined in Section 409A of the Internal Revenue Code and the regulations thereunder ("***Section 409A***"). Notwithstanding anything else provided herein, to the extent any payments provided under this RSU Agreement in connection with Participant's termination of employment constitute deferred compensation subject to Section 409A, and Participant is deemed at the time of such termination of employment to be a "specified employee" under Section 409A, then such payment shall not be made or commence until the earlier of (i) the expiration of the six-month period measured from Participant's separation from service from the Company or (ii) the date of Participant's death following such a separation from service; provided, however, that such deferral shall only be effected to the extent required to avoid adverse tax treatment to Participant including, without limitation, the additional tax for which Participant would otherwise be liable under Section 409A(a)(1)(B) in the absence of such a deferral. To the extent any payment under this RSU 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 section are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

23. Award Subject to Company Clawback or Recoupment. The RSUs shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of Participant's employment or other Service that is applicable to Participant. In addition to any other remedies available under such policy, applicable law may require the cancellation of Participant's RSUs (whether vested or unvested) and the recoupment of any gains realized with respect to Participant's RSUs.

BY ACCEPTING THIS AWARD OF RSUS, PARTICIPANT AGREES TO ALL OF THE TERMS AND CONDITIONS DESCRIBED ABOVE AND IN THE PLAN.

APPENDIX

ARCUTIS BIOTHERAPEUTICS, INC.
2022 EMPLOYMENT INDUCEMENT INCENTIVE PLAN
GLOBAL RESTRICTED STOCK UNIT AWARD AGREEMENT

COUNTRY SPECIFIC PROVISIONS FOR EMPLOYEES OUTSIDE THE U.S.

Not applicable

December 13, 2021

Masaru Matsuda
5123 Meadows Del Mar
San Diego, CA 92130

RE: Employment with Arcutis Biotherapeutics, Inc.

Dear Mas:

This employment letter sets forth the terms and confirms your employment as Senior Vice President and General Counsel with Arcutis Biotherapeutics, Inc., a Delaware Corporation (the "Company" or "Arcutis"). You will report to me, the Company's Chief Executive Officer. If you accept this offer, you will commence employment with the Company on January 3, 2022, or such other date mutually agreed in writing between you and the Company (the date you actually commence employment with the Company, the "Effective Date").

1. **Work Location**. The Company will allow you to work primarily from your home office. However, as Arcutis' headquarters are located in the Los Angeles, California area, you will be expected to spend a reasonable amount of time at the Company's headquarters. The Company will provide expense reimbursement for your visits to our Los Angeles area offices as outlined in section 4 of this agreement.

2. **Compensation**.

a) **Salary**. In this position, the Company will pay you an annual base salary of four hundred fifteen thousand dollars ($415,000) per year, payable in accordance with the Company's standard payroll schedule. Your pay will be periodically subject to adjustment pursuant to the Company's policies as in effect from time to time and pro-rated for any partial employment hereunder.

b) **Bonus.** You will be eligible to receive a cash incentive annual bonus with a target of forty percent (40%) of your base salary, with the possibility of up to sixty percent (60%) of your base salary, based upon the achievement of both corporate and personal goals. Any annual bonus earned will be paid no later than March 15th of the year following the year in which such bonus was earned and will be contingent upon your continued employment through the applicable payment date. Please note that bonus programs, payouts and criterion are subject to change or adjustment as the business needs at the Company may require.

c) **Equity Awards.** In connection with entering into this employment letter agreement, following the Effective Date, the Company will recommend to the Board of Directors that it grant you:

i. **Stock Options.** An option to purchase one hundred eighty-five thousand (185,000) shares of the Company's common stock (the "Stock Option") at a per-share exercise price equal to the fair market value of a share of the Company's common stock on the date of grant (the closing price of the Company's common stock as reported on the Nasdaq Global Select Market on the date of grant). The shares subject to the Stock Option will vest and become exercisable at the rate of twenty-five percent (25%) on the first anniversary of the Effective Date, and an additional 2.0833% per month thereafter, so long as you remain employed by the Company through the applicable vesting date.

ii. **Performance-Based Restricted Stock.** Thirty-nine thousand (39,000) Restricted Stock Units of the Company's common stock (the "RSUs"). The RSUs will vest and become exercisable as follows:

1) Upon approval by the Audit Committee of the commercial launch compliance program (expected within 30 days of the commercial launch date), nineteen thousand five hundred (19,500) of the RSUs will commence vesting at a rate of twenty-five percent (25%) annually, with the first 25% vesting on the date that the achievement of the performance criteria has been certified by the Compensation Committee, and the remaining shares vesting in equal installments on each subsequent one (1) year anniversary, so long as you remain employed by the Company through the applicable vesting date.

2) Upon execution of the first key payor contract with a top plan (e.g., Zinc or Ascent), nineteen thousand five hundred (19,500) of the RSUs will commence vesting at a rate of twenty-five percent (25%) annually, with the first 25% vesting on the date that the achievement of the performance criteria has been certified by the Compensation Committee, and the remaining shares vesting in equal installments on each subsequent one (1) year anniversary, so long as you remain employed by the Company through the applicable vesting date.

The Stock Options and Restricted Stock Units will otherwise be subject to the terms and conditions of the Company's 2022 Employment Inducement Plan (the "Plan") and a stock option agreement and/or restricted stock agreement(s) to be entered into between you and the Company. You may be eligible to receive such future stock options or restricted stock unit grants as the Board of Directors of the Company shall deem appropriate; however, the grant of such options or restricted stock units by the Company is not a promise of compensation and is not intended to create any obligation on the part of the Company.

In addition, you will not be disqualified from receiving an additional "annual" equity grant in 2022. For context, Company employees are normally not eligible to receive an "annual" equity grant unless they have been employed at the Company on September 30 of the prior year.

d) **Withholdings**. All forms of compensation paid to you as an employee of the Company shall be less all applicable withholdings.

3. **Employee Benefits**. You will be entitled to participate in employee benefit plans currently and hereafter maintained by the Company of general applicability to other employees of the Company subject to the eligibility requirements of each such benefit plan. The Company, in its sole discretion, may amend, suspend or terminate its employee benefits at any time, with or without notice. In addition, you will be entitled to paid vacation in accordance with the Company's vacation policy, as in effect from time to time. We also acknowledge that you have entered, or will enter, into the Severance and Change in Control Agreement with the Company (the "Severance & Change in Control Agreement").

4. **Expenses**.

a) The Company will reimburse Employee for reasonable travel, entertainment or other expenses incurred by Employee in the furtherance of or in connection with the performance of Employee's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

5. **Confidentiality Agreement**. As an employee of the Company, you will have access to certain confidential information of the Company and you may, during the course of your employment, develop certain information or inventions that will be the property of the Company. To protect the interests of the Company, you will need to sign the Company's standard "Employee Invention Assignment and Confidentiality Agreement" as a condition of your employment. We wish to impress upon you that we do not want you to, and we hereby direct you not to, bring with you any confidential or proprietary material of any former employer or to violate any other obligations you may have to any former employer. During the period that you render services to the Company, you agree to not engage in any employment, business or activity that is in any way competitive with the business or proposed business of the Company. You will disclose to the Company in writing any other gainful employment, business or activity that you are currently associated with or participate in that competes with the Company. You will not assist any other person or organization in competing with the Company or in preparing to engage in competition with the business or proposed business of the Company.

6. **No Conflicting Obligations**. You understand and agree that by signing this letter agreement, you represent to the Company that your performance will not breach any other agreement to which you are a party, including, without limitation, any agreement currently in place between your current or past employers, and that you have not, and will not during the term of your employment with the Company, enter into any oral or written agreement in conflict with any of the provisions of this letter or the Company's policies. You are not to bring with you to the Company, or use or disclose to any person associated with the Company, any confidential or proprietary information belonging to any former employer or other person or entity with respect to which you owe an obligation of confidentiality under any agreement or otherwise. The Company does not need and will not use such information and we will assist you in any way possible to preserve and protect the confidentiality of proprietary information belonging to third parties. Also, we expect you to abide by any obligations to refrain from soliciting any person employed by or otherwise associated with any former employer and suggest that you refrain from having any contact with such persons until such time as any non-solicitation obligation expires.

7. **Outside Activities**. While you render services to the Company, you agree that you will not engage in any other employment, consulting or other business activity without the written consent of the Company. In addition, while you render services to the Company, you will not assist any person or entity in competing with the Company, in preparing to compete with the Company or in hiring any employees or consultants of the Company.

8. **General Obligations**. As an employee, you will be expected to adhere to the Company's standards of professionalism, loyalty, integrity, honesty, reliability and respect for all. You will also be expected to comply with the Company's policies and procedures. The Company is an equal opportunity employer.

9. **At-Will Employment**. Employment with the Company is for no specific period of time. Your employment with the Company will be on an "at will" basis, meaning that either you or the Company may terminate your employment at any time for any reason or no reason. The Company also reserves the right to modify or amend the terms of your employment at any time for any reason. Any contrary representations which may have been made to you are superseded by this letter agreement. Further, your participation in ant stock option or benefit program is not to be regarded as assuring you of continuing employment for any particular period of time. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of your employment may only be changed in an express written agreement signed by you and the Company's Chief Executive Officer.

10. **Authorization to Work**. Please note that because of employer regulations adopted in the Immigration Reform and Control Act of 1986, within three (3) business days of starting your new position you will need to present documentation demonstrating that you have authorization to work in the United States.

11. **Arbitration and Class Action Waiver**. You and the Company agree to submit to mandatory binding arbitration any and all claims arising out of or related to your employment with the Company and the termination thereof, including, but not limited to, claims for unpaid wages, wrongful termination, torts, stock or stock options or other ownership interest in the Company, and/or discrimination (including harassment) based upon any federal, state or local ordinance, statute, regulation or constitutional provision except that each party may, at its, his or her option, seek injunctive relief in court related to the improper use, disclosure or misappropriation of a party's private, proprietary, confidential or trade secret information (collectively, "Arbitrable Claims"). Further, to the fullest extent permitted by law, you and the Company agree that no class or collective actions can be asserted in arbitration or otherwise. All claims, whether in arbitration or otherwise, must be brought solely in your or the Company's individual capacity, and not as a plaintiff or class member in any purported class or collective proceeding. Nothing in this Arbitration and Class Action Waiver section, however, restricts your right, if any, to file in court a representative action under California Labor Code Sections 2698, et seq.

SUBJECT TO THE ABOVE PROVISO, THE PARTIES HEREBY WAIVE ANY RIGHTS THEY MAY HAVE TO TRIAL BY JURY IN REGARD TO ARBITRABLE CLAIMS. THE PARTIES FURTHER WAIVE ANY RIGHTS THEY MAY HAVE TO PURSUE OR PARTICIPATE IN A CLASS OR COLLECTIVE ACTION PERTAINING TO ANY ARBITRABLE CLAIMS BETWEEN YOU AND THE COMPANY.

This Agreement does not restrict your right to file administrative claims you may bring before any government agency where, as a matter of law, the parties may not restrict the employee's ability to file such claims (including, but not limited to, the National Labor Relations Board, the Equal Employment Opportunity Commission and the Department of Labor). However, the parties agree that, to the fullest extent permitted by law, arbitration shall be the exclusive remedy for the subject matter of such administrative claims. The arbitration shall be conducted in Orange County, California through JAMS before a single neutral arbitrator, in accordance with the JAMS employment arbitration rules then in effect. The JAMS rules may be found and reviewed at http://www.jamsadr.com/rules-employment-

arbitration. If you are unable to access these rules, please let me know and I will provide you with a hardcopy. 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 employment letter agreement shall be construed in accordance with the laws of the State of California, without reference to conflicts of law principles.

12. **Entire Agreement**. This employment letter agreement, once accepted, together with the Severance & Change in Control Agreement and the Employee Invention Assignment and Confidentiality Agreement, constitute the entire agreement between you and the Company with respect to the subject matter hereof and supersedes all prior offers, negotiations and agreements, if any, whether written or oral, relating to such subject matter. You acknowledge that neither the Company nor its agents have made any promise, representation or warranty whatsoever, either express or implied, written or oral, which is not contained in this agreement for the purpose of inducing you to execute the agreement, and you acknowledge that you have executed this agreement in reliance only upon such promises, representations and warranties as are contained herein.

13. **Acceptance**. This offer will remain open until Friday, December 17, 2021. If you decide to accept our offer, and I hope you will, please sign the enclosed copy of this letter in the space indicated and return it to me. Your signature will acknowledge that you have read and understood and agreed to the terms and conditions of this offer letter and the attached documents, if any. Should you have anything else that you wish to discuss, please do not hesitate to call me.

We look forward to the opportunity to welcome you to the Company.

[SIGNATURE PAGE FOLLOWS]

This letter agreement supersedes and replaces any prior understandings or agreements, whether oral, written or implied, between you and the Company regarding the matters described in this letter. This letter will be governed by the laws of California, without regard to its conflict of laws provisions.

Very truly yours,

ARCUTIS BIOTHERAPEUTICS, INC.

By: /s/ Todd Franklin Watanabe
Title: Chief Executive Officer

ACCEPTED AND AGREED:

By: /s/ Mas Matsuda

Date: December 13, 2021

[Signature Page to Employment Letter Agreement]

Arcutis Biotherapeutics, Inc.
Severance & Change in Control Agreement

This Severance & Change in Control Agreement (the "**Agreement**"), is entered into by and between Masaru Matsuda (the "**Executive**") and Arcutis Biotherapeutics, Inc., a Delaware company (the "**Company**"), and is effective as of the date that this Agreement is signed (the "**Effective Date**").

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.

(i) "**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.**

(a) **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	ARCUTIS BIOTHERAPEUTICS, INC.
/s/ Masaru Matsuda	By: /s/ Frank Watanabe
Date: January 3, 2022	Title: President and Chief Executive Officer Date: January 2, 2022

[Signature Page to the Severance & Change in Control Agreement]

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may be amended, restated, modified, or supplemented from time to time, this "**Agreement**") dated as of December 22, 2021 (the "**Effective Date**") among SLR Investment Corp., a Maryland corporation with an office located at 500 Park Avenue, 3rd Floor, New York, NY 10022 ("**SLR**"), as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), and the lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including SLR in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and ARCUTIS BIOTHERAPEUTICS, INC., a Delaware corporation with offices located at 3027 Townsgate Road, Suite 300, Westlake Village, CA 91361 ("**Borrower**"), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. DEFINITIONS AND OTHER TERMS

1.1 Terms. Capitalized terms used herein shall have the meanings set forth in Section 1.4 to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the accompanying notes and schedules. For the avoidance of doubt, and without limitation of the foregoing, Permitted Convertible Indebtedness shall at all times be valued at the full stated principal amount thereof and shall not include any reduction or appreciation in value of the shares deliverable upon conversion thereof.

1.2 Section References. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified.

1.3 Divisions. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person, and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its equity interests at such time.

1.4 Definitions. The following terms are defined in the Sections or subsections referenced opposite such terms:

"**Agreement**"	Preamble
"**Approved Lender**"	Section 12.1
"**Borrower**"	Preamble
"**Change of Control**"	Section 7.2
"**Claims**"	Section 12.2
"**Collateral Agent**"	Preamble
"**Collateral Agent Report"**	Exhibit B, Section 5
"**Communications**"	Section 10
"**Connection Income Taxes**"	Exhibit C, Section 1
"**Data Protection Laws**"	Section 5.11(a)
"**Data Protection Requirements**"	Section 5.11(a)
"**Default Rate**"	Section 2.3(b)
"**Effective Date**"	Preamble
"**Event of Default**"	Section 8
"**Excluded Taxes**"	Exhibit C, Section 1
"**FATCA**"	Exhibit C, Section 1
"**Indemnified Person**"	Section 12.2
"**Indemnified Taxes**"	Exhibit C, Section 1
"**Lender**" and "**Lenders**"	Preamble
"**Lender Transfer**"	Section 12.1
"**New Subsidiary**"	Section 6.10
"**Non-Funding Lender**"	Exhibit B, Section 10(c)(ii)
"**Open-Source Licenses**"	Section 5.2(f)
"**Other Connection Taxes**"	Exhibit C, Section 1
"**Other Lender**"	Exhibit B, Section 10(c)(ii)
"**Other Taxes**"	Exhibit C, Section 1
"**Perfection Certificate**" and "**Perfection Certificates**"	Section 5.1
"**Participant Register**"	Section 12.1
"**Recipient**"	Exhibit C, Section 1
"**Register**"	Section 12.1
"**SLR**"	Preamble
"**Termination Date**"	Exhibit B, Section 8
"**Term Loan**"	Section 2.2(a)(iv)
"**Tranche A Term Loan**"	Section 2.2(a)(i)
"**Tranche B Term Loan**"	Section 2.2(a)(iii)
"**Tranche B-1 Term Loan**"	Section 2.2(a)(ii)
"**Tranche B-2 Term Loan**"	Section 2.2(a)(iii)
"**Tranche C Term Loan**"	Section 2.2(a)(iv)
"**Transfer**"	Section 7.1
"**U.S. Tax Compliance Certificate**"	Exhibit C, Section 7(b)(ii)(C)
"**Withholding Agent**"	Exhibit C, Section 1

In addition to the terms defined elsewhere in this Agreement, the following terms have the following meanings:

"**Account**" is any "account" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"**Account Debtor**" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**ACH Letter**" is ACH debit authorization in the form of Exhibit G hereto.

"**Affiliate**" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"**Anti-Terrorism Laws**" are any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"**Applicable Rate**" means a per annum interest rate equal to (a) seven and forty-five hundredths percent (7.45%) plus (b) the greater of (i) one-tenth percent (0.10%) and (ii) the rate per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (the "**Service**") (or on any successor or substitute page of such Service, or any successor to or substitute for such Service, as determined by Collateral Agent in a manner consistent with other loans in Collateral Agent's portfolio) for a term of one month, which determination by Collateral Agent shall be conclusive in the absence of manifest error; provided that if, at any time, Lenders notify Collateral Agent that Lenders have determined that (x) Lenders are unable to determine or ascertain such rate, (y) the applicable regulator has made public statements to the effect that the rate published by the Service is no longer used for determining interest rates for loans or (z) by reason of circumstances affecting the foreign exchange and interbank markets generally, deposits in eurodollars in the applicable amounts or for the relative maturities are not being offered for such period, then the Applicable Rate shall be equal to an alternate benchmark rate and spread agreed between Collateral Agent and Borrowers (which may include SOFR, to the extent publicly available quotes of SOFR exist at the relevant time), giving due consideration to (i) market convention or (ii) selection, endorsement or recommendation by a Relevant Governmental Body. Such alternative benchmark rate and spread shall be binding unless the Required Lenders object within five (5) days following notification of such amendment.

"**Approved Fund**" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

"**Average Market Capitalization**" means, for the applicable period of determination, the aggregate sum of the Market Capitalization for each trading day, during such period divided by the number of trading days in such period.

"**Blocked Person**" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"**Borrower's Books**" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, state, local and foreign tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which commercial banks in New York, New York are required or authorized to be closed.

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition and having a rating of at least A-2 or P-2 from either Standard & Poor's Ratings Group or Moody's Investors Services; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent, (d) any money market or similar funds under Borrower's investment policy, as approved by Collateral Agent from time to time, (e) corporate debt securities and similar securities having a rating of at least "A-/A-3" or above, from either Moody's, Fitch, or S&P, respectively and in each case maturing within eighteen (18) months after the date of creation or acquisition thereof, (f) direct obligations issued by any state, commonwealth or territory of the United States or any political subdivision or taxing authority thereof, in each case having a rating of at least "AAA" from Moody's, Fitch, or S&P with maturities within eighteen (18) months after the date of creation or acquisition thereof, and (g) any money market or similar funds that exclusively hold any of the foregoing.

"**CFC**" means a "controlled foreign corporation" as defined in Section 957 of the Internal Revenue Code.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

"**Commitment Percentage**" is set forth in Schedule 1.1, as amended from time to time.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Compliance Certificate**" is that certain certificate in substantially the form attached hereto as Exhibit E.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business.

The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith in accordance with GAAP; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Call Spread Agreement shall not constitute a Contingent Obligation of the Borrower.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower or such Subsidiary, as applicable, and Collateral Agent pursuant to which Collateral Agent, for the ratable benefit of the Secured Parties, obtains "control" (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Default**" is any event that, with the giving of notice or passage of time or both, could constitute an Event of Default.

"**Deposit Account**" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Designated Deposit Account**" is Borrower's deposit account, account number , maintained at Silicon Valley Bank.

"**Dollars**," "**dollars**" and "$" each mean lawful money of the United States.

"**Eligible Assignee**" is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars ($5,000,000,000.00), which in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower's Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture fund or a distressed debt fund, each as determined by Collateral Agent in its reasonable discretion. Notwithstanding the foregoing, (x) in connection with any assignment made by a Lender as a result of a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"**Excluded Subsidiary**" means each direct and indirect Subsidiary of Borrower (a) that is a CFC, (b) that is a direct or indirect Subsidiary of a CFC, or (c) substantially all of the assets of which are equity interests (or equity interests and debt interests) in one or more CFCs; in each case, provided that (i) the pledge of all of the equity interests of such Subsidiary as Collateral or (ii) the guarantee by such Subsidiary of the Obligations would result in material adverse tax consequences to Borrower (as reasonably determined by Borrower and Collateral Agent).

"**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

"**Exit Fee Agreement**" is that certain Exit Fee Agreement, dated as of the date hereof, by and among Collateral Agent, as agent, Borrower and the Lenders, as amended, amended and restated, supplemented or otherwise modified from time to time.

"**FDA**" means the U.S. Food and Drug Administration or any successor thereto.

"**Fee Letter**" means that certain Fee Letter, dated as of the date hereof, by and among Collateral Agent, as agent, Borrower and the Lenders, as amended, amended and restated, supplemented or otherwise modified from time to time.

"**Foreign Currency**" means lawful money of a country other than the United States.

"**Funding Date**" is any date on which a Term Loan is made to or on account of Borrower which shall be a Business Day.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination; provided that for purposes of the defined term "Permitted Indebtedness," GAAP shall be GAAP as in effect on the Effective Date.

"**General Intangibles**" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any federal, state, municipal, national or other government, governmental department, commission, board, bureau, court, agency or instrumentality or political subdivision thereof (including the FDA) or any entity or officer exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to any government or any court, in each case whether associated with a state or locality of the United States, the United States, or a foreign government.

"**Governmental Payor**" means, Medicare, Medicaid, TRICARE, CHAMPVA, any state health plan adopted pursuant to Title XIX of the Social Security Act, any other state or federal health care program and any other Governmental Authority which presently or in the future maintains a payment or reimbursement program, and in which Borrower or any Subsidiary participates.

"**Guarantor**" is any Person providing a Guaranty in favor of Collateral Agent for the benefit of the Secured Parties (including without limitation pursuant to Section 6.10).

"**Guaranty**" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Healthcare Laws**" means all applicable laws, rules and regulations relating to the provision or payment of health items and services applicable to the Borrower or its Subsidiaries, including, without limitation, (a) all federal and state 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 statements law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1347 and 1349, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. Section 1320d et seq.), any applicable state fraud and abuse prohibitions, including those that apply to all payors (governmental, commercial insurance and self-payors), the civil monetary penalty laws (42 U.S.C. § 1320a-7a), the exclusion laws (42 U.S.C. § 1320a-7), and any similar state laws or regulations, (b) any laws relating to any Governmental Payor, including, without limitation, the Medicare statute (Title XVIII of the Social Security Act) and the Medicaid statute (Title XIX of the Social Security Act), and (c) any and all other applicable health care laws, regulations and binding program manual provisions and transmittals, each of (a) through (c) as may be amended from time to time.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, (d) non-contingent obligations of such Person to reimburse any bank or other Person in respect of amounts paid under a letter of credit, banker's acceptance or similar instrument, (e) equity securities of such Person subject to repurchase or redemption other than at the sole option of such Person, (f) obligations secured by a Lien on any asset of such Person, whether or not such obligation is otherwise an obligation of such Person, (g) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature of such Person arising out of purchase and sale contracts, (h) all Indebtedness of others guaranteed by such Person, (i) off-balance sheet liabilities and/or pension plan or multiemployer plan liabilities of such Person, and (j) Contingent Obligations. Notwithstanding anything to the contrary in the foregoing, any Permitted Call Spread Agreement shall not constitute Indebtedness of the Borrower.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"**Intellectual Property**" means all of Borrower's or any of its Subsidiaries' right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"**Intellectual Property Security Agreement**" means that certain Intellectual Property Security Agreement dated as of the Effective Date between Borrower and Collateral Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

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

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"**IRS**" means the United States Internal Revenue Service.

"**Key Person**" is each of Borrower's (i) President and Chief Executive Officer, who is Frank Watanabe as of the Effective Date, (ii) Chief Financial Officer, who is Scott Burrows as of the Effective Date, and (iii) Chief Technical Officer, who is David Osborne as of the Effective Date, and (iv) Chief Medical Officer, who is Patrick Burnett, MD, PhD, FAAD as of the Effective Date.

"**Knowledge**" means to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

"**Lender**" is any one of the Lenders.

"**Lenders**" are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"**Lenders' Expenses**" are (a) all reasonable audit fees and expenses, costs, and expenses (including reasonable attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating and administering the Loan Documents, and (b) all fees and expenses (including attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents. The diligence deposit paid by the Borrower to the Collateral Agent prior to the Effective Date shall be applied to the Lenders' Expenses.

"**Lien**" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Documents**" are, collectively, this Agreement, the Exit Fee Agreement, the Fee Letter, each Control Agreement, the Intellectual Property Security Agreement, the Perfection Certificates, each Compliance Certificate, the ACH Letter, each Loan Payment Request Form, any Guarantees, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, any agreements creating or perfecting rights in the Collateral (including all insurance certificates and endorsements, landlord consents and bailee consents) and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent, as applicable, in connection with this Agreement; all as amended, restated, or otherwise modified.

"**Loan Parties**" means the Borrower and the Guarantors, and "**Loan Party**" shall mean any one of them.

"**Loan Payment Request Form**" is that certain form attached hereto as Exhibit D.

"**Market Capitalization**" means, as of any date of determination, the product of (a) the number of Borrower's shares of common stock disclosed in the most recent filing of Borrower as outstanding as of such date of determination and (b) the closing price of Borrower's shares of common stock listed on the Securities and Exchange Commission (as quoted on Securities and Exchange Commission page or any successor page thereto or if such page is not available, any other commercially available source providing quotations of such closing price as reasonably selected by Borrower) on such date of determination.

"**Material Adverse Change**" is (a) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower and its Subsidiaries, when taken as a whole; or (b) a material impairment of (i) the ability of the Loan Parties to repay any portion of the Obligations, (ii) the legality, validity or enforceability of any Loan Document, (iii) the rights and remedies of Collateral Agent or Lenders under any Loan Document except as the result of the action or inaction of the Collateral Agent or Lenders or (iv) the validity, perfection or priority of any Lien in favor of Collateral Agent for the benefit of the Secured Parties on any of the Collateral except as the result of the action or inaction of the Collateral Agent or Lenders. For the avoidance of doubt, "Material Adverse Change" shall not include, in and of themselves, the non-occurrence of any of the events as described under "Tranche B Term Loan Funding Condition" or "Tranche C Term Loan Funding Condition".

"**Material Agreement**" is any license, agreement or other contractual arrangement of Borrower or any of its Subsidiaries whereby Borrower or any of its Subsidiaries is required to file and disclose such license, agreement, or contractual arrangement with the Securities and Exchange Commission.

"**Maturity Date**" is, for each Term Loan, January, 1 2027.

"**Net Product Revenue**" means the net product revenue, determined in accordance with GAAP, from the sale of any products of Borrower or its Subsidiaries, inclusive of Borrower's share of sales generated indirectly through the sales of Borrower's products under any licensing or similar arrangement and which amounts are included in the net product revenue of Borrower in accordance with GAAP.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Premium, all fees under the Fee Letter and the Exit Fee Agreement, and any other amounts Borrower owes the Collateral Agent or the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent in connection with this Agreement and the other Loan Documents, and the performance of Borrower's duties under the Loan Documents.

"**OFAC**" is the U.S. Department of Treasury Office of Foreign Assets Control.

"**OFAC Lists**" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, re-examination certificates, utility models, extensions and continuations-in-part of the same.

"**Payment Date**" is the first (1st) calendar day of each calendar month, commencing on February 1, 2022.

"**Permitted Acquisition**" means any consensual transaction or series of related transactions for the direct or indirect (a) acquisition by Borrower of all or substantially all of the assets of, all of the ownership interests in, or a business line or unit or division of another Person, including any foreign corporations in the acceptable jurisdictions listed below in this definition and (b) acquisition of any intellectual property and related ancillary rights or assets of any person; provided that:

(a) No Default or Event of Default shall exist immediately before or immediately after the consummation of such acquisition;

(b) such acquired Person or assets (other than non-core assets, if any, with respect to such acquisition) shall be in a business of the type permitted pursuant to Section 7.2(a);

(c) such acquisition shall not cause the focus or locations of Borrower's and its Subsidiaries' operations (when taken as a whole) to be located outside of the United States;

(d) such acquisition shall not constitute a hostile acquisition;

(e) all transactions in connection therewith shall be consummated, in all material respects, in accordance with all applicable Requirement of Laws and in conformity with all applicable Governmental Approvals;

(f) in the case of the acquisition of the equity interests of such Person, all of the equity interests acquired, or otherwise issued by such Person or any newly formed Subsidiary of Borrower in connection with such acquisition, shall be directly or indirectly owned one hundred percent (100%) by Borrower, and Borrower shall have taken, or caused to be taken, each of the actions set forth in Section 6.10, if applicable within the applicable time periods set forth therein;

(g) in connection with such acquisition, neither Borrower nor any of its Subsidiaries (including for this purpose, the target of the acquisition) shall acquire or be subject to any Indebtedness or Liens that are not otherwise permitted hereunder;

(h) the sum of the purchase price of such proposed new acquisition, computed on the basis of total acquisition consideration paid or incurred, or to be paid or incurred, by Borrower with respect thereto, including, "earnouts", any other contingent or deferred acquisition consideration (provided that such "earnouts" and any other contingent or deferred acquisition consideration shall be unsecured (other than escrow arrangements securing indemnification obligations associated with such acquisition)), and including the amount of Permitted Indebtedness assumed or to which such assets, businesses or business or ownership interest or shares, or any Person so acquired, is subject, shall not be greater than Twenty Million Dollars ($20,000,000.00) in cash for any single acquisition or group of related acquisitions for each fiscal year or Thirty Million Dollars ($30,000,000.00) in cash for all such acquisitions during the term of this Agreement, in each case plus reasonable closing costs incurred in connection with such acquisition;

(i) on or prior to the proposed date of consummation of such transaction, the Borrower shall have delivered to the Collateral Agent and the Lenders a certificate of a Responsible Officer of the Borrower certifying that such transaction complies with this definition;

(j) Borrower has notified the Lenders at least ten (10) Business Days in advance of entering into such transaction, which notice shall include a reasonably detailed description of such transaction;

(k) substantially all of the assets and operations involved in such transaction shall be located in the United States; provided that, notwithstanding the foregoing, intellectual property (including in-licensing and products) and related ancillary rights and assets involved in such transaction may be located in the United States or outside of the United States so long as the acquired intellectual property (including in-licensing and products) and related ancillary rights and assets involved in such transaction are acquired as property of a Loan Party;

(l) Borrower has provided evidence satisfactory to Collateral Agent demonstrating that immediately following the consummation of such acquisition and after giving pro forma effect to the payment of all acquisition consideration (including all "earnouts" and any other contingent or deferred acquisition consideration regardless of whether such consideration is paid upon or consummation or payable thereafter) in connection therewith, Borrowers will have sufficient cash runway for the immediately succeeding twelve (12) month period based upon projections calculated in good faith by Borrower and agreed to by Collateral Agent;

(m) to the extent that the consideration for any such acquisition includes stock or similar equity interests, the payment of such consideration in the form of stock or similar equity shall not result in a Change of Control; and

(n) Borrower shall provide to the Collateral Agent as soon as available but in any event not later than five (5) Business Days after the execution thereof, a copy of the executed purchase agreement or similar agreement with respect to any such acquisition.

"**Permitted ARQ Licenses**" licenses for the use of ARQ-151 and ARQ-154; provided, that, with respect to each such license (i) the license constitutes an arms-length transaction, (ii) the terms, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; provided, however, that in the case of exclusive licenses for any non-United States jurisdiction, Borrower or such Subsidiary may covenant in such exclusive license that it will not license such intellectual property to another Person in the specific geography for which such license applies, (iii) the license is limited to territory outside of the United States, (iv) there is not an ongoing Event of Default at the time of the execution of the license, and (v) the license does not restrict the Borrower's ability to pledge, grant a security interest in or Lien on, or assign, or otherwise transfer Borrower's interest in any Intellectual Property.

"**Permitted Call Spread Agreements**" means (a) any call option transaction (including, but not limited to, any bond hedge transaction or capped call transaction) pursuant to which the Borrower acquires an option requiring the counterparty thereto to deliver to the Borrower shares of common stock of the Borrower (or other securities or property following a merger event or other change of the common stock of the Borrower), the cash value thereof or a combination thereof from time to time upon exercise of such option entered into by the Borrower in connection with the issuance of Permitted Convertible Indebtedness (such transaction, a "**Bond Hedge Transaction**") and (b) any call option transaction pursuant to which the Borrower issues to the counterparty thereto warrants to acquire common stock of the Borrower (or other securities or property following a merger event or other change of the common stock of the Borrower) (whether such warrant is settled in shares, cash or a combination thereof) entered into by the Borrower in connection with the issuance of Permitted Convertible Indebtedness (such transaction, a "**Warrant Transaction**"); provided that (i) the terms, conditions and covenants of each such call option transaction are customary for agreements of such type, as determined by Borrower in good faith, and (ii) the purchase price for such Bond Hedge Transaction, less the proceeds received by the Borrower from the sale of any related Warrant Transaction, does not exceed twenty percent (20%) of the aggregate principal amount of the related Permitted Convertible Indebtedness at the time of such purchase.

"**Permitted Convertible Indebtedness**" means senior unsecured notes issued by the Borrower pursuant to either an effective registration statement under the Securities Act of 1933, as amended or Rule 144A of the regulations thereunder (which issuance shall include a customary offering document which describes (i) this Agreement and (ii) the capital structure of Borrower after giving effect to such Indebtedness, in each case, in reasonable detail as determined by the Borrower in good faith) that are convertible into a fixed number (subject to customary anti-dilution adjustments, "make-whole" increases and the other customary changes thereto) of shares of common stock of the Borrower (or other securities or property following a merger event or other change of the common stock of the Borrower), cash or any combination thereof (with the amount of such cash or such combination determined by reference to the market price of such common stock or such other securities) and cash in lieu of fractional shares of common stock of the Borrower; provided that the Indebtedness thereunder must satisfy each of the following conditions, and any agreements providing for such Indebtedness may only be amended, restated, supplemented or modified from time to time if each of the following conditions remains satisfied: (i) both immediately prior to and after giving effect (including pro forma effect) thereto, no Default or Event of Default shall exist or result therefrom, (ii) such Indebtedness matures, and does not provide for or require any scheduled amortization or other scheduled or otherwise provided for or required payments of principal or interest prior to, after the date that is one hundred eighty (180) days after the Maturity Date (it being understood that neither (x) any provision requiring an offer to purchase such Indebtedness as a result of change of control or other fundamental change (howsoever defined), (y) any early conversion of such Indebtedness in accordance with the terms thereof, nor (z) any provision providing for redemption of such Indebtedness upon satisfaction of a condition related to the stock price of the Borrower's common stock, in each case, shall violate the foregoing restriction), (iii) Borrower's market capitalization, as of the close of the regular trading session for the Borrower's common stock on the date that is one (1) Business Day prior to the date of launching (i.e. not pricing) of such convertible Indebtedness, is not less than Four Hundred Million Dollars ($400,000,000.00), (iv) such Indebtedness (at any one time outstanding) is in an aggregate principal amount of not more than Three Hundred Million Dollars ($300,000,000.00), (v) such Indebtedness shall bear an interest rate of not more than seven and one half percent (7.50%) per annum and the terms, conditions and covenants (other than pricing terms determined through a customary marketing process) of such Indebtedness must be customary for convertible Indebtedness of such type (as determined by the Borrower in good faith) and (vi) such Indebtedness is not guaranteed by any Subsidiary of the Borrower (unless the Obligations are guaranteed by such Subsidiary on a secured basis).

"**Permitted Indebtedness**" is:

(o) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(p) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate;

(q) Subordinated Debt;

(r) unsecured Indebtedness to trade creditors incurred in the ordinary course of business

(s) unsecured Indebtedness in connection with credit cards incurred in the ordinary course of business in an aggregate amount not to exceed Five Hundred Thousand Dollars ($500,000.00);

(t) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets or software of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed One Million Dollars ($1,000,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(u) Permitted Convertible Indebtedness;

(h) Indebtedness consisting of the obligation to pay rent when due under real property leases entered into in the ordinary course of Borrower's business;

(i) other unsecured Indebtedness at any time not to exceed One Million Dollars ($1,000,000.00) in the aggregate;

(j) Indebtedness in respect of letters of credit, bank guarantees and similar instruments issued for the account of the Borrower or any of its Subsidiaries in the aggregate amount not to exceed Three Million Dollars ($3,000,000.00) at any time, in each case as incurred in the ordinary course of business;

(k) Hedges and similar transactions with respect to currency risk entered into in the ordinary course of business and not for speculative purposes;

(l) Surety bonds and similar Indebtedness entered into in the ordinary course of business and in an amount not exceeding One Million Dollars ($1,000,000.00) outstanding at any time;

(m) Intercompany Indebtedness that constitutes a Permitted Investment under clause (f), (i) and (j) of the term "Permitted Investments";

(n) Advances or deposits received from customers or vendors in the ordinary course of business;

(o) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature of such Person arising out of purchase and sale contracts (including any indemnification and other similar obligations incurred in an acquisition), in each case subject to the limitations in the definition of "Permitted Acquisition";

(p) Indebtedness arising in connection with the financing of insurance premiums in an amount not exceeding One Million Dollars ($1,000,000.00) outstanding at any time;

(q) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business; and

(r) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (p) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

"**Permitted Investments**" are:

(a) Investments disclosed on the Perfection Certificate and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of Deposit Accounts in which Collateral Agent has a perfected Lien (subject to the terms of this Agreement) for the ratable benefit of the Secured Parties except as permitted in Section 6.6 hereof;

(e) Investments in connection with Permitted Indebtedness, Permitted Liens and with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's board of directors; not to exceed Five Hundred Thousand Dollars ($500,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(i) Investments in Subsidiaries that are Guarantors;

(j) Investments in Subsidiaries that are not Guarantors, not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00) per fiscal year;

(k) Permitted Acquisitions;

(l) any Permitted Call Spread Agreements; and

(m) (i) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support, and (ii) Investments in joint ventures or strategic alliances; provided that with respect to such Investments under this sub-clause (ii), the aggregate outstanding amount of all such cash Investments made during any fiscal year shall not exceed Two Million Dollars ($2,000,000.00); and

(n) other Investments not to exceed One Million Dollars ($1,000,000.00) in the aggregate outstanding at any time.

"**Permitted Licenses**" are (A) licenses of over-the-counter software that is commercially available to the public, (B) non-exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (C) exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in this clause (C), the license (i) constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property (provided, however, Borrower or such Subsidiary may covenant in such license that it will not license such intellectual property to another Person in the specific geography for which such license applies), and (ii) is limited in territory with respect to a specific geographic country or region (i.e. Japan, Germany, northern China) outside of the United States, and (D) Permitted ARQ Licenses.

"**Permitted Liens**" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificate or arising under this Agreement and the other Loan Documents;

(b) Liens for Taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith by appropriate proceedings diligently conducted and for which Borrower maintains adequate reserves on Borrower's Books in accordance with GAAP, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code and the Treasury Regulations adopted thereunder;

(c) Liens securing Indebtedness permitted under clause (e) of the definition of "Permitted Indebtedness," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, landlords, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Five Hundred Thousand Dollars ($500,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(a) hereof;

(i) Liens on cash that stand as security for letter of credit reimbursement obligations and cash management obligations, together with such amount permitted under clause (j) of "Permitted Liens", in the aggregate amount not to exceed Three Million Dollars ($3,000,000.00);

(j) Security deposits under real property leases that are made in the ordinary course of business, together with such amount permitted under clause (i) of "Permitted Liens", in the aggregate amount not to exceed Three Million Dollars ($3,000,000.00);

(k) Liens on proceeds of insurance and unpaid premiums to secure Indebtedness permitted under clause (o) of the defined term "Permitted Indebtedness" not to exceed One Million Dollars ($1,000,000.00);

(l) To the extent constituting a Lien, escrow arrangements securing indemnification obligations associated with any Permitted Acquisition;

(m) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(n) Permitted Licenses; and

(o) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described above, but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Prepayment Premium**" is, with respect to any Term Loan subject to prepayment, refinancing, substitution or replacement prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise (including, but not limited to, upon the occurrence of a bankruptcy or insolvency event (including the acceleration of claims by operation of law)), an additional fee payable to the Lenders in amount equal to:

(a) for a prepayment, refinancing, substitution or replacement made on or after the Effective Date through but excluding the first anniversary of the Effective Date, three percent (3.00%) of the principal amount of such Term Loan so prepaid;

(b) for a prepayment, refinancing, substitution or replacement made on or after the date which is the first anniversary of the Effective Date through but excluding the second anniversary of the Effective Date, two percent (2.00%) of the principal amount of such Term Loan so prepaid;

(c) for a prepayment, refinancing, substitution or replacement made on or after the date which is after the second anniversary of the Effective Date through and excluding the fourth anniversary of the Effective Date, one percent (1.00%) of the principal amount of such Term Loan so prepaid; and

(d) for a prepayment, refinancing, substitution or replacement made on or after the date which is the fourth anniversary of the Effective Date and prior to the Maturity Date, zero percent (0.00%) of the principal amount of such Term Loan so prepaid.

"**Property**" means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"**Redemption Conditions**" means, with respect to any redemption by the Borrower of any Permitted Convertible Indebtedness, satisfaction of each of the following events: (a) no Event of Default has occurred and is continuing or result therefrom, (b) both immediately before and after such redemption, the aggregate amount of all cash and Cash Equivalents held in Collateral Accounts subject to a Control Agreement in favor of Collateral Agent shall be no less than an amount equal to the product of (i) one hundred fifty percent (150%) and (ii) the amount required to prepay the outstanding Obligations in full at the time of such redemption, including, for the avoidance of doubt, all outstanding principal of the Term Loans, the accrued and unpaid interest thereon, the Prepayment Premium, all fees under the Fee Letter, and (c) a Responsible Officer has provided a certificate to the Collateral Agent not less than five (5) Business Days prior to such redemption certifying that each of the foregoing events is satisfied, together with reasonably detailed calculations in support thereof.

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Registration**" means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA or state pharmacy licensing authorities (including, without limitation, new drug applications, abbreviated new drug applications, investigational new drug applications, pricing and reimbursement approvals, labelling approvals or their foreign equivalent, and wholesale distributor permits).

"**Regulatory Action**" means an administrative, regulatory, or judicial enforcement action, proceeding, for-cause investigation or inspection, FDA Form 483 notice of inspectional observation, warning letter, untitled letter, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, injunction or consent decree, issued by the FDA or a federal or state court.

"**Related Persons**" means, with respect to any Person, each Affiliate of such Person and each director, officer, employee, agent, trustee, representative, attorney, accountant and each insurance, environmental, legal, financial and other advisor and other consultants and agents of or to such Person or any of its Affiliates.

"**Relevant Governmental Body**" means the Federal Reserve Board, the Federal Reserve Bank of New York, and/or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York, or any successor thereto.

"**Required Lenders**" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "**Original Lender**") have not assigned or transferred any of their interests in their Term Loan other than to an Affiliate of such Lender, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding more than fifty percent (50%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"**Responsible Officer**" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower.

"**Secured Parties**" means the Collateral Agent and the Lenders.

"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**SOFR**" means the daily Secured Overnight Financing Rate provided by the Federal Reserve Bank of New York as the administrator of the benchmark (or a successor administrator) on the Federal Reserve Bank of New York's Website.

"**Solvent**" means, with respect to any Person, that (a) the fair saleable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities, (b) such Person is not left with unreasonably small capital giving effect to the transactions contemplated by this Agreement and the other Loan Documents, and (c) such Person is able to pay its debts (including trade debts) as they mature in the ordinary course (without taking into account any forbearance and extensions related thereto).

"**Subordinated Debt**" is unsecured indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders which (i) is non-cash pay (other than any customary fees and expenses) during the term of this Agreement, (ii) has a maturity date outside the date that is one hundred eighty (180) days after the Maturity Date, (iii) is unsecured, and (iv) is subject to a subordination, intercreditor, or other similar agreement providing for deep subordination (including with respect to payment (other than customary fees and expenses), and enforcement) in form and substance reasonably satisfactory to Collateral Agent and the Required Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor.

"**Subsidiary**" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"**Taxes**" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1**.**

"**Term Loan Commitments**" means the aggregate amount of such commitments of all Lenders.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower and each of its Subsidiaries connected with and symbolized by such trademarks.

"**Tranche B Term Loan Condition**" is Collateral Agent's receipt of, by no later than December 15, 2022, satisfactory evidence that Borrower has received FDA approval of ARQ-151 (Topical Roflumilast Cream) for an indication relating to the treatment of patients with plaque psoriasis (such FDA approval, the "ARQ-151 FDA Approval").

"**Tranche B-1 Term Loan Draw Period**" is the period commencing on the Effective Date and ending on the earlier of (i) the date which is fifteen (15) days after Borrower has received the ARQ-151 FDA Approval and (ii) June 30, 2023.

"**Tranche B-2 Term Loan Draw Period**" is the period commencing on the Effective Date and ending on June 30, 2023.

"**Tranche C Term Loan Condition**" is Collateral Agent's receipt of satisfactory evidence that Borrower has achieved a minimum of One Hundred Ten Million Dollars ($110,000,000.00) in Net Product Revenue calculated on a trailing six (6) month basis.

"**Tranche C Term Loan Draw Period**" is the period commencing on the Effective Date and ending on September 30, 2024.

"**Unqualified Opinion**" means an opinion on financial statements from an independent certified public accounting firm reasonably acceptable to Collateral Agent which opinion shall not include any qualification expressing substantial doubt about the ability of Borrower or any of its Subsidiaries to continue as a going concern or any qualification or exception as to the scope of such audit; provided that an opinion shall continue to be an Unqualified Opinion if the opinion includes going concern explanatory language solely in connection with the Borrower's cash levels or liquidity, the pending maturity of the Borrower's indebtedness within the next twelve (12) months, and/or the financial covenants hereunder.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability.

(i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate principal amount of Seventy-Five Million Dollars ($75,000,000.00) according to each Lender's Tranche A Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Tranche A Term Loan**", and collectively as the "**Tranche A Term Loans**"). After repayment, no Tranche A Term Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Tranche B-1 Term Loan Draw Period, to make term loans to Borrower in an aggregate principal amount of Fifty Million Dollars ($50,000,000.00), and disbursed in a single advance according to each Lender's Tranche B Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Tranche B-1 Term Loan**", and collectively as the "**Tranche B-1 Term Loans**"). After repayment, no Tranche B-1 Term Loan may be re-borrowed.

(iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Tranche B-2 Term Loan Draw Period, to make term loans to Borrower in an aggregate principal amount of up to Seventy-Five Million Dollars ($75,000,000.00), in minimum increments of Fifteen Million Dollars ($15,000,000.00), according to each Lender's Tranche B Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Tranche B-2 Term Loan**", and collectively as the "**Tranche B-2 Term Loans**"; each Tranche B-1 Term Loan or Tranche B-2 Term Loan is hereinafter referred to singly as a "**Tranche B Term Loan**" and the Tranche B-1 Term Loans and the Tranche B-2 Term Loans are hereinafter referred to collectively as the "**Tranche B Term Loans**"). After repayment, no Tranche B-2 Term Loan may be re-borrowed

(iv) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Tranche C Term Loan Draw Period, to make term loans to Borrower in an aggregate principal amount of up to Twenty-Five Million Dollars ($25,000,000.00), and disbursed in a single advance according to each Lender's Tranche C Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Tranche C Term Loan**", and collectively as the "**Tranche C Term Loans**"; each Tranche A Term Loan, Tranche B Term Loan or Tranche C Term Loan is hereinafter referred to singly as a "**Term Loan**" and the Tranche A Term Loans, Tranche B Term Loans and Tranche C Term Loans are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Tranche C Term Loan may be re-borrowed.

(b) Repayment. Commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, Borrower shall make monthly payments of interest, to each Lender in accordance with its Pro Rata Share, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon the effective rate of interest applicable to such Term Loan, as determined in Section 2.3(a). All unpaid principal and accrued and unpaid interest with respect to each such Term Loan is due and payable in full on the Maturity Date, to each Lender in accordance with its Pro Rata Share. The Term Loans may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated (including, but not limited to, upon the occurrence of a bankruptcy or insolvency event (including the acceleration of claims by operation of law)), Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) any fees payable under the Fee Letter by reason of such prepayment, (iii) the Prepayment Premium, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if any fees payable under the Fee Letter by reason of such prepayments had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to each Lender such fees as may then be due and payable in accordance with the terms of the Fee Letter. The Prepayment Premium shall also be payable in the event the Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other means. EACH BORROWER AND GUARANTOR EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE FOREGOING PREPAYMENT PREMIUM IN CONNECTION WITH ANY SUCH ACCELERATION. Notwithstanding anything to the contrary herein, there shall be no Prepayment Premium due and payable by Borrower to the Lenders hereunder if Borrower prepays all, but not less than all, of the outstanding Term Loans in connection with new loans made by SLR or any Affiliate of SLR.

(d) Permitted Prepayment of Term Loans. Borrower shall have the option to prepay any portion of the outstanding principal balance of the Term Loans advanced by the Lenders under this Agreement; in minimum increments of Five Million Dollars ($5,000,000.00), provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least five (5) Business Days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the outstanding principal of the Term Loans or portion(s) thereof being prepaid plus accrued and unpaid interest thereon through the prepayment date, (B) any fees payable under the Fee Letter by reason of such prepayment, (C) the Prepayment Premium, plus (D) all other Obligations that are due and payable on such prepayment date, including any Lenders' Expenses and interest at the Default Rate (if any) with respect to any past due amounts.

2.3 Payment of Interest on the Term Loans.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Applicable Rate in effect from time to time, as determined by Collateral Agent on the third Business Day prior to the Funding Date of the applicable Term Loan and on the date occurring on the first Business Day of the month prior to each Payment Date occurring thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Except as set forth in Section 2.2(b), such interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full (or any date on which partial payment is made).

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, all Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus four percentage points (4.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year for the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Person's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds. Collateral Agent may at its discretion and with prior notice of at least (x) with respect to the immediately following sub-clauses (i) and (ii) ten (10) Business Days and (y) with respect to the immediately following sub-clause (iii), one (1) Business Day, initiate debit entries to the Borrower's account as authorized on the ACH Letter (i) on each payment date of all Obligations then due and owing, (ii) at any time any payment due and owing with respect to Lender Expenses, and (iii) upon an Event of Default, any other Obligations outstanding.

2.4 Fees. Borrower shall pay to Collateral Agent and/or Lenders (as applicable) the following fees, which shall be deemed fully earned and non-refundable upon payment:

(a) Fee Letter. When due and payable under the terms of the Fee Letter, to Collateral Agent and each Lender, as applicable, the fees set forth in the Fee Letter.

(b) Prepayment Premium. The Prepayment Premium, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares. Borrower expressly agrees (to the fullest extent that each may lawfully do so) that: (i) the Prepayment Premium is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (ii) the Prepayment Premium shall be payable notwithstanding the then prevailing market rates at the time payment is made; (iii) there has been a course of conduct between Collateral Agent, Lenders and Borrower giving specific consideration in this transaction for such agreement to pay the Prepayment Premium and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this paragraph. Borrower expressly acknowledges that its agreement to pay the Prepayment Premium to Lenders as herein described is a material inducement to Lenders to provide the Term Loan Commitments and make the Term Loans.

(c) Lenders' Expenses. All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due; provided that, the aggregate amount of Lenders' Expenses incurred on or prior to the Effective Date shall not exceed Three Hundred Thousand Dollars ($300,000.00).

2.5 Taxes; Increased Costs. Borrower, Collateral Agent and the Lenders each hereby agree to the terms and conditions set forth on Exhibit C attached hereto.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Term Loan. Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;

(b) a completed Perfection Certificate for Borrower and each of its Subsidiaries;

(c) duly executed Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries to the extent required under Section 6.6;

(d) a duly executed Fee Letter;

(e) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date**;**

(f) a certificate of Borrower in substantially the form of Exhibit F hereto executed by the Secretary of Borrower with appropriate insertions and attachments, including with respect to (i) the Operating Documents of Borrower (which Certificate of Incorporation of Borrower shall be certified by the Secretary of State of the State of Delaware) and (ii) the resolutions adopted by Borrower's board of directors for the purpose of approving the transactions contemplated by the Loan Documents;

(g) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan, will be terminated or released;

(h) a duly executed legal opinion of counsel to Borrower dated the Effective Date;

(i) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Secured Parties;

(j) [Reserved];

(k) [Reserved]; and

(l) payment of the fees payable under the terms of the Fee Letter and Lenders' Expenses then due as specified in Section 2.4 hereof.

3.2 Conditions Precedent to all Term Loans. The obligation of each Lender to extend each Term Loan, including the initial Term Loan, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Loan Payment Request Form in the form of Exhibit D attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the Funding Date of each Term Loan; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the funding of such Term Loan;

(c) in such Lender's reasonable discretion, there has not been any Material Adverse Change;

(d) No Event of Default or Default, shall exist;

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.4 hereof (including payment of the fees payable under the terms of the Fee Letter);

(f) with respect to any Tranche B Term Loan, the Tranche B Term Loan Condition shall be satisfied; and

(g) with respect to any Tranche C Term Loan, the Tranche C Term Loan Condition shall be satisfied.

3.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Term Loan. Borrower expressly agrees that a Term Loan made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Term Loan in the absence of a required item shall be made in each Lender's sole discretion.

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan (other than the Term Loan funded on the Effective Date), Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 p.m. New York City time three (3) Business Days prior to the date the applicable Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to Collateral Agent by electronic mail or facsimile a completed Loan Payment Request Form executed by a Responsible Officer or his or her designee. The Collateral Agent may rely on any telephone notice given by a person whom Collateral Agent reasonably believes is a Responsible Officer or designee.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Secured Parties, to secure the payment and performance in full of all of the Obligations in full and, until payment in cash of all Obligations (other than (a)(i) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made, and (b) all obligations under the Exit Fee Agreement), a continuing first priority security interest in, and pledges to Collateral Agent, for the ratable benefit of the Secured Parties, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products and supporting obligations (as defined in the Code) in respect thereof. If Borrower shall acquire any commercial tort claim (as defined in the Code) in an amount greater than Fifty Thousand Dollars ($50,000.00), Borrower shall grant to Collateral Agent, for the ratable benefit of the Secured Parties, a first priority security interest therein and in the proceeds and products and supporting obligations (as defined in the Code) thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than (a)(i) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made, and (b) all obligations under the Exit Fee Agreement) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than (a) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made, and (b) all obligations under the Exit Fee Agreement) and at such time as the Lenders' obligation to extend Term Loans has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral (and enter into any related documentation reasonably requested by Borrower) and all rights therein shall revert to Borrower.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral (held for the ratable benefit of the Secured Parties), without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents. Such financing statements may include an indication that the financing statement covers "all assets or all personal property" of such Loan Party in accordance with Section 9-504 of the Code.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be so qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate and any updates or supplements thereto on, before or after the Effective Date (each a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). For the avoidance of doubt, Collateral Agent and Lenders agree that the Borrower may from time-to-time update certain information in the Perfection Certificates after the Effective Date to the extent permitted by one or more specific provisions in this Agreement. Borrower represents and warrants that all the information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries is accurate and complete (other than clerical mistakes in addresses and other contact information).

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is, or they are, a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such

Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any Material Agreement by which Borrower, any of its Subsidiaries or any of their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any Material Agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 Collateral.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith in respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein as required under this Agreement. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that, under applicable law, have priority over Collateral Agent's Lien.

(c) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee, and (ii) no such third party bailee possesses components of the Collateral in excess of One Million Dollars ($1,000,000.00) in book value.

(d) All Inventory and Equipment is in all material respects of good and marketable quality, free from material defects.

(e) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property (other than Intellectual Property that has no material value) each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificate on the Effective Date, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other Material Agreement.

5.3 Litigation. Except as disclosed on the Perfection Certificate or with respect to which Borrower has provided notice as required hereunder, there are no actions, suits, investigations, or proceedings pending or, to the Knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than One Million Dollars ($1,000,000.00).

5.4 No Material Adverse Change; Financial Statements. All consolidated financial statements for Borrower and its consolidated Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, and in all material respects the consolidated financial condition of Borrower and its consolidated Subsidiaries, and the consolidated results of operations of Borrower and its consolidated Subsidiaries. Since December 31, 2020, there has not been a Material Adverse Change.

5.5 Solvency. Borrower is Solvent. Borrower and each of its Subsidiaries, when taken as a whole, is Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term

is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's Knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the Knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries have timely filed all required tax returns and reports (or extensions thereof), and Borrower and each of its Subsidiaries have timely paid all foreign, federal, state, and local Taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries in an amount greater than Fifty Thousand Dollars ($50,000.00), in all jurisdictions in which Borrower or any such Subsidiary is subject to Taxes, including the United States, unless such Taxes are being contested in accordance with the next sentence. Borrower and each of its Subsidiaries may defer payment of any contested Taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the Taxes by appropriate proceedings promptly and diligently instituted and conducted; (b) notifies Collateral Agent of the commencement of, and any material development in, the proceeding; and (c) maintains adequate reserves or other appropriate provisions on its books in accordance with GAAP, provided, further, that such action would not involve, in the reasonable judgment of Collateral Agent, any risk of the sale, forfeiture or loss of any material portion of the Collateral. Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiary's prior Tax years which could result in additional Taxes greater than Fifty Thousand Dollars ($50,000.00) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries has withdrawn from participation in, has permitted partial or complete termination of, or has permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Term Loans to repay existing Indebtedness, as working capital (including, without limitation, to fund Permitted Acquisitions) and to fund its general business requirements, and not for personal, family, household or agricultural purposes.

5.10 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement, when taken as a whole, given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed

as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.11 [Reserved].

5.12 Healthcare Regulatory Matters.

(a) Borrower and each Subsidiary is in compliance with all applicable Healthcare Laws, the noncompliance with which could reasonably be expected to have a Material Adverse Change, and, during the past three (3) years, to Borrower's knowledge, none of Borrower or its Subsidiaries have engaged in activities which are, as applicable, cause for civil penalties, or mandatory or permissive exclusion from any Governmental Payor which could reasonably be expected to have a Material Adverse Change. Without limiting the generality of the foregoing, during the past three (3) years, none of Borrower or its Subsidiaries has received written notice by a Governmental Authority of any violation (or of any investigation, audit, or other proceeding involving allegations of any violation) of any Healthcare Laws which could reasonably be expected to have a Material Adverse Change, and no such investigation, inspection, audit or other proceeding involving allegations of any such violation is, to Borrower's Knowledge, threatened in writing or contemplated which could reasonably be expected to have a Material Adverse Change.

(b) Borrower and each Subsidiary, and its respective officers, directors, and employees are not and, during the past three (3) years, has not been, excluded, debarred, suspended or otherwise ineligible to participate in any Governmental Payor where the same could reasonably be expected to have a Material Adverse Change, and no such action is pending or, to Borrower's Knowledge, threatened in writing. None of the Borrower or its Subsidiaries: (i) is a party to or has any reporting obligations under a corporate integrity agreement, deferred or non-prosecution agreement, monitoring agreement, consent decree, settlement order, or any similar agreement with any Governmental Authority; or (ii) during the past three (3) years, has made or been the subject of any submissions pursuant to the Office of Inspector General's Self Disclosure Protocol.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Other than specifically permitted hereunder, maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations, including all Healthcare Laws, to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Secured Parties, in all of the Collateral.

6.2 Financial Statements, Reports, Certificates; Notices.

(a) Deliver to Collateral Agent:

(i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, and income statement, subject to quarter- and year-end adjustments and the absence of footnotes, covering the consolidated operations of Borrower and its consolidated Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to the Collateral Agent;

(ii) as soon as available, but no later than forty-five (45) days after the last day of each of Borrower's fiscal quarters, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its consolidated Subsidiaries for such fiscal quarter certified by a Responsible Officer and in a form reasonably acceptable to the Collateral Agent;

(iii) as soon as available, but no later than ninety (90) days after the last day of Borrower's fiscal year or within five (5) days of filing of the same with the SEC, audited consolidated financial statements covering the consolidated operations of Borrower and its consolidated Subsidiaries for such fiscal year, prepared under GAAP, consistently applied, together with an Unqualified Opinion on the financial statements;

(iv) as soon as available after approval thereof by Borrower's board of directors, but no later than the earlier of (x) ten (10) days' after such approval and (y) February 28 of such year, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's board of directors; provided that, any revisions to such projections approved by Borrower's board of directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(v) together with the delivery of the Compliance Certificate, copies of all non-ministerial material statements, reports and notices made available generally to Borrower's security holders or holders of Subordinated Debt (other than materials provided to members of the Borrower's board of directors solely in their capacities as security holder, holders of Subordinated Debt, board members or management of Borrower); provided, however, the foregoing may be subject to such exclusions and redactions as Borrower deems reasonably necessary, in the exercise of its good faith judgment, in order to (i) preserve the confidentiality of highly sensitive information, (ii) prevent impairment of the attorney client privilege or (iii) conflict of interest with Lenders for new financing;

(vi) within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission;

(vii) prompt notice of any amendments of or other changes to the respective Operating Documents of Borrower or any of its Subsidiaries, in each case together with any copies reflecting such amendments or changes with respect thereto;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s);

(ix) [Reserved];

(x) prompt delivery of (and in any event within five (5) days after the same are sent or received) copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or that otherwise could reasonably be expected to have a Material Adverse Change;

(xi) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the value of the Intellectual Property or (B) could reasonably be expected to result in a Material Adverse Change;

(xii) written notice delivered at least five (5) Business Days' prior to Borrower's creation of a New Subsidiary in accordance with the terms of Section 6.10;

(xiii) written notice delivered at least twenty (20) days' prior to Borrower's (A) adding any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Five Hundred Thousand Dollars ($500,000.00) in assets or property

of Borrower or any of its Subsidiaries), (B) changing its respective jurisdiction of organization, (C) changing its organizational structure or type, (D) changing its respective legal name, or (E) changing any organizational number(s) (if any) assigned by its respective jurisdiction of organization;

(xiv) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within three (3) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, and Borrower's proposal regarding how to cure such Event of Default or event;

(xv) immediate notice if Borrower or such Subsidiary has Knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering;

(xvi) notice of any commercial tort claim (as defined in the Code) or letter of credit rights (as defined in the Code) held by Borrower or any Guarantor, in each case in an amount greater than Five Hundred Thousand Dollars ($500,000.00) and of the general details thereof;

(xvii) if Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, written notice of such occurrence and information regarding such Person's organizational identification number within seven (7) Business Days of receiving such organizational identification number;

(xviii) prompt notice of the execution any Material Agreement or any amendment to, modification of, termination of or waiver under any Material Agreement; and

(xix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, the materials required to be delivered pursuant to clauses (ii), (iii), (vi) and (xviii) above may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to Collateral Agent:

(i) a duly completed Compliance Certificate signed by a Responsible Officer;

(ii) copies of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries;

(iii) written notice of the commencement of, and any material development in, the proceedings contemplated by Section 5.8 hereof;

(iv) prompt written notice of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of One Million Dollars ($1,000,000.00); and

(v) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than One Million Dollars ($1,000,000.00) individually or in the aggregate in any calendar year.

(c) Keep proper, complete and true books of record and account in accordance with GAAP in all material respects. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, as applicable, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices, as applicable.

6.4 Taxes; Pensions. Timely file, and require each of its Subsidiaries to timely file (or obtain timely extensions therefor), all required tax returns and reports, and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state, and local Taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except as otherwise permitted pursuant to the terms of Section 5.8 hereof; deliver to the Collateral Agent, on demand, appropriate certificates attesting to such payments; and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are standard for companies in Borrower's industry and location. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and shall waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent (for the ratable benefit of the Secured Parties), as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be cancelled (except in the case of non-payment). At Collateral Agent's request, Borrower shall deliver to the Collateral Agent certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Secured Parties, on account of the then-outstanding Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy within one-hundred eighty (180) days of receipt thereof up to Two Million Dollars ($2,000,000.00) with respect to any loss, but not exceeding Two Million Five Hundred Thousand Dollars ($2,500,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement promptly or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent may make (but has no obligation to do so), at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent deems prudent.

6.6 Operating Accounts.

(a) Maintain Borrower's and Guarantors Collateral Accounts with depositary institutions that have agreed to execute Control Agreements in favor of Collateral Agent with respect to such Collateral Accounts. The provisions of the previous sentence shall not apply to Deposit Accounts exclusively used for cash collateral for Permitted Liens under clause (i) of the definition thereof, payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any Guarantor's, employees, in an aggregate amount not to exceed the amount reasonably expected to be due and payable for the next two (2) succeeding pay periods to Collateral Agent by Borrower as such in the Perfection Certificate.

(b) Borrower shall provide Collateral Agent ten (10) days' prior written notice before Borrower or any Guarantor establishes any Collateral Account. In addition, for each Collateral Account that Borrower or any Guarantor, at any time maintains, Borrower or such Guarantor shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account (held for the ratable benefit of the Secured Parties) in accordance with the terms hereunder prior to the establishment of such Collateral Account. The provisions of the previous sentence shall not apply to Deposit Accounts exclusively used for cash collateral for Permitted Liens under clause (i) of the definition thereof, payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any Guarantor's, employees and identified to Collateral Agent by Borrower as such in the Perfection Certificate, provided that the amount deposited therein shall not exceed the amount reasonably expected to be due and payable for the next two (2) succeeding pay periods.

(c) Neither Borrower nor any Guarantor shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with this Section 6.6.

6.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall: (a) protect, defend and maintain the validity and enforceability of its respective Intellectual Property that is material to its business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its respective Intellectual Property; and (c) not allow any of its respective Intellectual Property material to its respective business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent with respect to any Collateral or relating to Borrower.

6.9 Landlord Waivers; Bailee Waivers. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then, in the event that the Collateral at any new location is valued (based on book value) in excess of One Million Dollars ($1,000,000.00) in the aggregate, at Collateral Agent's election, Borrower shall use commercially reasonable efforts to cause such bailee or landlord, as applicable, to execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be; provided, that this Section 6.9 shall not be applicable to any locations owned or controlled by any contract research organization.

6.10 Creation/Acquisition of Subsidiaries. In the event any Borrower or any Subsidiary of any Borrower creates or acquires any Subsidiary after the Effective Date, Borrower or such Subsidiary shall promptly notify the Collateral Agent of such creation or acquisition, and Borrower or such Subsidiary shall take all actions reasonably requested by the Collateral Agent to achieve any of the following with respect to such "**New Subsidiary**" (defined as a Subsidiary formed after the date hereof

during the term of this Agreement): (i) if such New Subsidiary is not an Excluded Subsidiary, to cause such New Subsidiary to become either a co-Borrower hereunder, or a secured guarantor with respect to the Obligations; and (ii) to grant and pledge to Collateral Agent a perfected security interest in (A) one hundred percent (100%) of the stock, units or other evidence of ownership held by Borrower or its Subsidiaries of any such New Subsidiary that is not an Excluded Subsidiary, or (B)(1) sixty-five percent (65%) of the stock, units or other evidence of ownership which entitle the holder thereof to vote for directors or any other matter and (2) one hundred percent (100%) of the stock, units or other evidence of ownership which do not entitle the holder thereof to vote for directors or any other matter, in each case held by Borrower or its Subsidiaries of any such New Subsidiary which is an Excluded Subsidiary. Notwithstanding the foregoing, immediately upon any change in the U.S. tax laws that would (i) result in such New Subsidiary ceasing to be an Excluded Subsidiary, Borrower shall cause such New Subsidiary to become either a co-Borrower hereunder or a secured guarantor with respect to the Obligations, or (ii) allow the pledge of a greater percentage of such voting equity interests of such New Subsidiary without material adverse tax consequences to Borrower, Borrower shall cause to be granted and pledged to Collateral Agent a perfected security interest in such greater percentage of voting equity interests of such New Subsidiary, in each case from that time forward.

6.11 Further Assurances. Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

6.12 Post-Effective Date Obligations. Notwithstanding any provision herein or in any other Loan Document to the contrary, to the extent not actually delivered on or prior to the Effective Date, the Borrowers shall, and shall cause each applicable Subsidiary to:

(a) deliver to Collateral Agent insurance endorsements, in each case satisfying the requirements of Section 6.5 within thirty (30) days of the Effective Date (as may be extended by Collateral Agent in its sole discretion).

(b) use commercially reasonable efforts to deliver to Collateral Agent a landlord's consent executed in favor of Collateral Agent in respect Borrower's leased location at 3027 Townsgate Road Suite 300, Westlake Village, CA 91361 no later than sixty (60) days after the Effective Date (as may be extended by Collateral Agent in its sole discretion)

(c) use commercially reasonable efforts to deliver to Collateral Agent a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of One Million Dollars ($1,000,000.00) in the aggregate no later than sixty (60) days after the Effective Date (as may be extended by Collateral Agent in its sole discretion); provided that this Section 6.12(c) shall not apply to any locations owned or controlled by any contract research organization.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, dispose of, license (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out, surplus, uneconomic or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) cash or Cash Equivalents pursuant to transactions not prohibited by this Agreement, (e) sales or discounting of delinquent accounts in the ordinary course of business; or (f) other Transfers not to exceed One Million Dollars ($1,000,000.00) during the term of this Agreement.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower or such Subsidiary, as applicable, as of the Effective Date or reasonably related, complimentary or incidental thereto; (b) liquidate or dissolve; or (c) (i) permit any Key Person to cease being actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within ten (10) Business Days of such cessation, or (ii) enter into any transaction or series of related transactions in which (any of the following, a "Change of Control") (A) the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty-five percent (45%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions, (B) that is a change of control or other fundamental change (howsoever defined) under the indenture governing any Permitted Convertible Indebtedness and (C) except as permitted by Section 7.3, Borrower ceases to own, directly or indirectly, one hundred percent (100%) of the ownership interests in each Subsidiary of Borrower. Borrower shall not, and shall not permit any of its Subsidiaries to, without at least twenty (20) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than One Million Dollars ($1,000,000.00) in assets or property of Borrower or any of its Subsidiaries, as applicable); (B) change its respective jurisdiction of organization, (C) except as permitted by Section 7.3, change its respective organizational structure or type, (D) change its respective legal name, or (E) change any organizational number(s) (if any) assigned by its respective jurisdiction of organization.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or shares or any property of another Person (other than Permitted Acquisitions), in each case including for the avoidance of doubt through a merger, purchase, in-licensing arrangement or any similar transaction. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder in accordance with Section 6.10) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Secured Parties) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens".

7.6 Maintenance of Collateral Accounts. With respect to Borrower and any Guarantors, maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 Restricted Payments. (a) Declare or pay any dividends (other than dividends payable solely in capital stock) or make any other distribution or payment in respect of or redeem, retire or purchase any capital stock or Permitted Convertible Indebtedness (other than (i) the declaration or payment of dividends to Borrower or its Subsidiaries, (ii) so long as no Default or Event of Default exists or would result therefrom, the declaration or payment of any dividends solely in the form of equity securities, and (iii) repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed Five Hundred Thousand Dollars ($500,000.00) in the aggregate per fiscal year), (b) other than the Obligations in accordance with the terms hereof, purchase, redeem, defease or prepay any principal of, premium, if any, interest or other amount payable in respect of any Indebtedness prior to its scheduled maturity unless being replaced with Indebtedness of at least the same principal amount and such new Indebtedness is Permitted Indebtedness, or (c) be a party to or bound

by an agreement that restricts a Subsidiary from paying dividends or otherwise distributing property to Borrower other than this Agreement or any equity or organizational documents of Borrower or such Subsidiary.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.7 shall not prohibit (i) the conversion by holders (including any cash payment upon conversion) of, or required payment of any principal or premium on, or required payment of any interest with respect to, any Permitted Convertible Indebtedness, in each case, in accordance with the terms of the indenture governing such Permitted Convertible Indebtedness; *provided* that this clause (i) shall only allow principal payments with respect to any repurchase in connection with the redemption of Permitted Convertible Indebtedness upon satisfaction of a condition related to the stock price of the Borrower's common stock if the Redemption Conditions are satisfied in respect of such redemption, or (ii) any required payment with respect to, or required early unwind or settlement of, any Permitted Call Spread Agreement, in each case, in accordance with the terms of the agreement governing such Permitted Call Spread Agreement.

Notwithstanding the restriction in Section 7.7, the Borrower may redeem, repurchase, exchange or induce the conversion of Permitted Convertible Indebtedness by delivery of shares of the Borrower's common stock and/or a different series of Permitted Convertible Indebtedness (which series (x) matures after, and does not require any scheduled amortization or other scheduled payments of principal prior to, the analogous date under the indenture governing the Permitted Convertible Indebtedness that are so repurchased, exchanged or converted and (y) has terms, conditions and covenants that are no less favorable to the Borrower than the Permitted Convertible Indebtedness that is so repurchased, exchanged or converted (as determined by the Borrower in good faith)) (any such series of Permitted Convertible Indebtedness, "**Refinancing Convertible Indebtedness**") and/or by payment of cash (in an amount that does not exceed the proceeds received by the Borrower from the substantially concurrent issuance of shares of the Borrower's common stock and/or a Refinancing Convertible Indebtedness plus the net cash proceeds, if any, received by the Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Call Spread Agreements pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the Permitted Convertible Indebtedness that is so repurchased, exchanged or converted, the Borrower shall (and, for the avoidance of doubt, shall be permitted under this Section 7.7 to) exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Call Spread Agreements, if any, corresponding to such Permitted Convertible Indebtedness that is so repurchased, exchanged or converted.

7.8 Investments. Directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so other than Permitted Investments.

7.9 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, and (c) compensation arrangements for Borrower's and its Subsidiaries' officers, directors and employees that are customary in Borrower's industry and approved by Borrower's board of directors.

7.10 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.11 Compliance. (a) Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Term Loan for that purpose; (b) fail to meet the minimum funding requirements of ERISA; (c) permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; (d) fail to comply with the Federal Fair Labor

Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; or (e) withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.12 Compliance with Anti-Terrorism Laws. Directly or indirectly, knowingly or permit any Affiliate to enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Directly or indirectly or permit any Affiliate to, (a) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (b) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (c) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

7.13 Financial Covenant. Permit Net Product Revenue, measured at the end of the applicable month beginning with the month ending December 31, 2023, to be lower than the Net Product Revenue set forth opposite the applicable month end for the applicable measuring periods as provided on Schedule 7.13 attached hereto; provided, however, that for any such month where Borrower's Average Market Capitalization measured over the trailing five (5) day period prior to the last day of such month is greater than or equal to Four Hundred Million Dollars ($400,000,000.00), this covenant shall not apply.

1.14 [Reserved.]

7.15 Redemption of Permitted Convertible Debt. Exercise any redemption right with respect to any Permitted Convertible Indebtedness upon satisfaction of a condition related to the stock price of the Borrower's common stock, unless the Redemption Conditions are satisfied in respect of such redemption.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Term Loan on its due date, or (b) pay any other Obligation within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof);

8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Landlord Waivers; Bailee Waivers), 6.10 (Creation/Acquisition of Subsidiaries) or Borrower violates any provision in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document to which such person is a party, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within twenty (20) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the twenty (20) day period or cannot after diligent attempts by Borrower or such Subsidiary, as applicable, be cured within such twenty (20) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such

reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Term Loans shall be made during such cure period).

8.3 Material Adverse Change. A Material Adverse Change has occurred;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment (other than Permitted Lien) is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) of this clause (a) are not, within twenty (20) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any material part of its business;

8.5 Insolvency. (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Term Loans shall be extended while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is a default and such default continues (after the applicable grace, cure or notice period) in (a) any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of One Million Dollars ($1,000,000.00) or that could reasonably be expected to have a Material Adverse Change, or (b) any indenture governing any Permitted Convertible Indebtedness. For the avoidance of doubt, (x) the exchange, repurchase, conversion or settlement with respect to any Permitted Convertible Indebtedness, or satisfaction of any condition giving rise to or permitting the foregoing, pursuant to their terms that does not result from a default thereunder or an event of the type that constitutes an Event of Default, or (y) any early payment requirement or unwinding or termination with respect to any Permitted Call Spread Agreement, or satisfaction of any condition giving rise to or permitting the foregoing, in accordance with the terms thereof where neither the Borrower nor any of its Affiliates is the "defaulting party" (or substantially equivalent term) under the terms of such Permitted Call Spread Agreement, in each case, shall not constitute an Event of Default under this Section 8.6.

8.7 Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least One Million Dollars ($1,000,000.00) (not covered by independent third-party insurance as to which (a) Borrower reasonably believes such insurance carrier will accept liability, (b) Borrower or the applicable Subsidiary has submitted such claim to such insurance carrier and (c) liability has not been rejected by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of thirty (30) days after the entry thereof;

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or the Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made;

8.9 Subordinated Debt. After giving effect to any grace or cure period, an event of default occurs under any subordination agreement with Collateral Agent, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect other than as a result of a transaction permitted under this Agreement; (b) any Guarantor does not perform any obligation or covenant under any Guaranty, after any applicable grace or cure period; (c) any circumstance described in Section 8 occurs with respect to any Guarantor, beyond any applicable grace or cure period;

8.11 Governmental Approvals; FDA Action. (a) Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or (b) (i) the FDA, DOJ or other Governmental Authority initiates a Regulatory Action or any other enforcement action against Borrower or any of its Subsidiaries or any supplier of Borrower or any of its Subsidiaries that causes Borrower or any of its Subsidiaries to recall, withdraw, remove or discontinue manufacturing, distributing, and/or marketing any of its products to the extent such action could reasonably be expected to result in a Material Adverse Change, even if such action is based on previously disclosed conduct; (ii) the FDA or any other comparable Governmental Authority issues a warning letter to Borrower or any of its Subsidiaries with respect to any of its activities or products which could reasonably be expected to result in a Material Adverse Change; (iii) Borrower or any of its Subsidiaries conducts a mandatory or voluntary recall which could reasonably be expected to result in a Material Adverse Change; (iv) Borrower or any of its Subsidiaries enters into a settlement agreement with the FDA, DOJ or other Governmental Authority that results in a Material Adverse Change, even if such settlement agreement is based on previously disclosed conduct; or (v) the FDA or any other comparable Governmental Authority revokes any authorization or permission granted under any Registration, or Borrower or any of its Subsidiaries withdraws any Registration, and such revocation or withdrawal that could reasonably be expected to result in a Material Adverse Change.

8.12 Lien Priority. Except as the result of the action or inaction of the Collateral Agent or the Lenders, any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien (to the extent required to be perfected) on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens arising as a matter of applicable law or that are explicitly permitted to have priority pursuant to this Agreement.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall at the written direction of Required Lenders, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) make a demand for payment upon any Guarantor pursuant to the Guaranty delivered by such Guarantor;

(iii) apply to the Obligations any (A) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, (B) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower, or (C) amounts received from any Guarantors in accordance with the respective Guaranty delivered by such Guarantor; and/or

(iv) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its Liens in the Collateral (held for the ratable benefit of the Secured Parties). Borrower shall assemble the Collateral if Collateral Agent requests and make it available at such location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, any of the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any Collateral Account maintained with Collateral Agent or any Lender or otherwise in respect of which a Control Agreement has been delivered in favor of Collateral Agent (for the ratable benefit of the Secured Parties) and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence and during the continuance of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts of Borrower directly with the applicable Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than (a)(i) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made, and (b) all obligations under the Exit Fee Agreement) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make extend Term Loans hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than (a)(i) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made, and (b) all obligations under the Exit Fee Agreement) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Term Loans terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other Obligations owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to the Lenders' Pro Rata Shares unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's Pro Rata Share of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be

responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its Pro Rata Share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other the Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its Pro Rata Share, then the portion of such payment or distribution in excess of such Lender's Pro Rata Share shall be received and held by such Lender in trust for and shall be promptly paid over to the other Lenders (in accordance with their respective Pro Rata Shares) for application to the payments of amounts due on such other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for the Secured Parties for purposes of perfecting Collateral Agent's security interest therein (held for the ratable benefit of the Secured Parties).

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or by Borrower or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and non-payment, notice of any default, non-payment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

Other than as specifically provided herein, all notices, consents, requests, approvals, demands, or other communication (collectively, "**Communications**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:	ARCUTIS BIOTHERAPEUTICS, INC. 3027 Townsgate Road, Suite 300 Westlake Village, CA 913361 Attn: Scott Burrows, Chief Financial Officer Fax: Email:
with a copy (which shall not constitute notice) to:	LATHAM & WATKINS LLP 140 Scott Drive Menlo Park, CA 94025 Attn: Fax: Email:
If to Collateral Agent:	SLR INVESTMENT CORP. 500 Park Avenue, 3rd Floor New York, NY 10022 Attention: Fax: Email:
with a copy (which shall not constitute notice) to:	DLA PIPER LLP (US) 500 8th Street, NW Washington, DC 20004 Attn: Fax: Email:

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

11.1 Waiver of Jury Trial. EACH OF BORROWER, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/ OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

11.2 Governing Law and Jurisdiction. THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND

PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

11.3 Submission to Jurisdiction. Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the State of New York located in the City of New York, Borough of Manhattan, or of the United States of America for the Southern District of New York and, by execution and delivery of this Agreement, Borrower hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against Borrower (or any property of Borrower) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of *forum non conveniens*, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

11.4 Service of Process. Borrower irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law, including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of Borrower specified herein (and shall be effective when such mailing shall be effective, as provided therein). Borrower agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

11.5 Non-exclusive Jurisdiction. Nothing contained in this Article 11 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against Borrower in any other jurisdiction.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in **(any** such sale, transfer, assignment, negotiation**,** or grant of a participation, a **"Lender Transfer")** all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided*, *however*, that any such Lender Transfer (other than (i) any Transfer at any time that an Event of Default has occurred and is continuing, or (ii) a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Collateral Agent (such approved assignee, an "**Approved Lender**"); and provided, further, that on the date it becomes a party to this Agreement, an Approved Lender (other than an Approved Lender that became a party to this Agreement by a Transfer at any time that an Event of Default has occurred and is continuing) must be capable, through its applicable lending office, of receiving payments of interest from Borrower without the imposition of any withholding taxes that would be required to be borne by Borrower or requiring the payment of any additional amounts by Borrower pursuant to Section 2.5 hereof. Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Collateral Agent shall use commercially reasonable efforts to provide notice to Borrower of each Lender Transfer promptly following such Lender Transfer, except for Lender Transfers an Affiliate of a Lender. Notwithstanding

anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture fund or distressed debt fund, each as determined by Collateral Agent in its reasonable discretion at the time of such assignment. Collateral Agent, acting solely for this purpose as an agent of Borrower, shall maintain at one of its offices in the United States a register for the recordation of the names and addresses of the Lenders, and the Term Loan Commitments of, and principal amounts (and stated interest) of the Term Loans owing to each Lender pursuant to the terms hereof from time to time (the "**Register**"). The entries in the Register shall be conclusive absent manifest error, and Borrower, Collateral Agent and Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by Borrower and any Lender at any reasonable time and from time to time upon reasonable prior notice. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Term Loans or other obligations under the Loan Documents (the "**Participant Register**"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, Collateral Agent (in its capacity as Collateral Agent) shall have no responsibility for maintaining a Participant Register. Borrower agrees that each participant shall be entitled to the benefits of the provisions in Exhibit C attached hereto (subject to the requirements and limitations therein, including the requirements under Section 7 of Exhibit C attached hereto (it being understood that the documentation required under Section 7 of Exhibit C attached hereto shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to this Section 12.1; provided that such participant shall not be entitled to receive any greater payment under Exhibit C attached hereto, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation.

12.2 Indemnification. Borrower agrees to indemnify, defend and hold each Secured Party and their respective directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing such Secured Party (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses and Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents (including reasonable attorneys' fees and expenses), except, in each case, for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further agrees to indemnify, defend and hold each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits,

claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

12.3 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.4 Correction of Loan Documents. Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties**.**

12.5 Amendments in Writing; Integration. No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its Guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Sections 12.7 or 12.8. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the immediately preceding sentence.

(b) Other than as expressly provided for in Section 12.5(a)(i)-(iii), Collateral Agent may, at its discretion, or if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.6 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

12.7 Survival. Except as otherwise provided in this Agreement, all covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than (a)(i) inchoate indemnity obligations, and (ii) any other obligations which, by their terms, are to survive the termination of this Agreement, and (b) all obligations under the Exit Fee Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.8 Confidentiality. In handling any confidential information of Borrower, each of the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loans (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, rule, regulation, regulatory or self-regulatory authority, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and/or Collateral Agent, as applicable, with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent through no breach of this provision by the Lenders or the Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis so long as, to the extent such client databases, reporting purposes and market analysis are disclosed publicly, the Collateral Agent and the Lenders do not disclose the identity of the Borrower or the identity of any person associated with the Borrower. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.8 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.8.

12.9 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a Lien, security interest and right of set off as security for all Obligations to Secured Parties hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of any Secured Party or any entity under the control of such Secured Party (including an Affiliate of Collateral Agent) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, any Secured Party may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY BORROWER.

12.10 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment (or portion thereof) or Term Loan (or portion thereof) to an assignee in accordance with Section 12.1, (ii) make Borrower's management personnel available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments, the Term Loans or portions thereof (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent and the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment (or portions thereof) or Term Loan (or portions thereof) as Collateral Agent or such Lender may reasonably may request. Subject to the provisions of Section 12.8, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment (or portions thereof), any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement, in each case subject to Section 12.8.

12.11 Public Announcement. Borrower hereby agrees that Collateral Agent and each Lender, may, make a public announcement of the transactions contemplated by this Agreement, and may publicize the same in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames and logos; provided that until such time as the initial public announcement of the transaction contemplated by this Agreement has been made, Collateral Agent and each Lender agree that it shall only make such public announcement or other publicization with the consent of Borrower (which consent may not be unreasonably conditioned, withheld or delayed). Notwithstanding the foregoing, such consent from Borrower shall not be required for any disclosures by Collateral Agent and the Lenders required by the Securities and Exchange Commission or other governmental agency and any other public disclosure with investors, other governmental agencies or other related persons, in each case, subject to applicable law and regulations.

12.12 Collateral Agent and Lender Agreement. Collateral Agent and the Lenders hereby agree to the terms and conditions set forth on Exhibit B attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Exhibit B attached hereto.

12.13 Time of Essence. Time is of the essence for the performance of Obligations under this Agreement.

12.14 Termination Prior to Maturity Date; Survival. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to its terms and all Obligations have been satisfied (other than (a)(i) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made, and (b) all obligations under the Exit Fee Agreement). So long as Borrower has satisfied the Obligations (other than (a)(i) inchoate indemnity obligations, and (ii) any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made, and (b) all obligations under the Exit Fee Agreement) in accordance with the terms of this Agreement, this Agreement may be terminated prior to the Maturity Date by Borrower, effective five (5) Business Days after written notice of termination is given to the Collateral Agent and the Lenders.

12.15 Electronic Execution of Certain Other Documents. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Collateral Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

ARCUTIS BIOTHERAPEUTICS, INC.

By /s/ Scott Burrows_____

Name: Scott Burrows
Title: Chief Financial Officer

COLLATERAL AGENT AND LENDER:

SLR INVESTMENT CORP.

By /s/ Anthony Storino_____

Name: Anthony Storino
Title: Authorized Signatory

LENDERS:

SLR SENIOR INVESTMENT CORP.,
as a Lender

By /s/ Anthony Storino_____
Name: Anthony Storino
Its: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV LLC,
as a Lender

By /s/ Anthony Storino_____
Name: Anthony Storino
Its: Authorized Signatory

SCP PRIVATE CREDIT INCOME BDC SPV LLC,
as a Lender

By /s/ Anthony Storino_____
Name: Anthony Storino
Its: Authorized Signatory

SCP PRIVATE CORPORATE LENDING FUND SPV LLC,
as a Lender

By /s/ Anthony Storino_____
Name: Anthony Storino
Its: Authorized Signatory

SCP SF DEBT FUND L.P.,
as a Lender

By /s/ Anthony Storino
Name: Anthony Storino
Its: Authorized Signatory

SLR HC FUND SPV, LLC,
as a Lender

By /s/ Anthony Storino
Name: Anthony Storino
Its: Authorized Signatory

SLR HC BDC LLC,
as a Lender

By /s/ Anthony Storino
Name: Anthony Storino
Its: Authorized Signatory

SCHEDULE 1.1

Lenders and Commitments

Tranche A Term Loans

Lender	Tranche A Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$21,735,086.09	28.98%
SLR SENIOR INVESTMENT CORP.	$3,333,333.33	4.44%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	$12,325,996.08	16.43%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$9,195,136.66	12.26%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$11,972,660.25	15.96%
SCP SF DEBT FUND L.P.	$2,877,005.95	3.84%
SLR HC FUND SPV, LLC	$11,202,765.00	14.94%
SLR HC BDC LLC	$2,358,016.64	3.14%
TOTAL	**$75,000,000.00**	**100.00%**

Tranche B Term Loans

Lender	Tranche B Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$36,225,143.46	28.98%
SLR SENIOR INVESTMENT CORP.	$5,555,555.56	4.44%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	$20,543,326.79	16.43%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$15,325,227.77	12.26%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$19,954,433.76	15.96%
SCP SF DEBT FUND L.P.	$4,795,009.92	3.84%
SLR HC FUND SPV, LLC	$18,671,275.01	14.94%
SLR HC BDC LLC	$3,930,027.73	3.14%
TOTAL	**$125,000,000.00**	**100.00%**

Tranche C Term Loans

Lender	Tranche C Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$7,245,028.70	28.98%
SLR SENIOR INVESTMENT CORP.	$1,111,111.11	4.44%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	$4,108,665.36	16.43%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$3,065,045.55	12.26%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$3,990,886.75	15.96%
SCP SF DEBT FUND L.P.	$959,001.98	3.84%
SLR HC FUND SPV, LLC	$3,734,255.00	14.94%
SLR HC BDC LLC	$786,005.55	3.14%
TOTAL	**$25,000,000.00**	**100.00%**

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$65,205,258.25	28.98%
SLR SENIOR INVESTMENT CORP.	$10,000,000.00	4.44%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	$36,977,988.23	16.43%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$27,585,409.98	12.26%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$35,917,980.76	15.96%
SCP SF DEBT FUND L.P.	$8,631,017.85	3.84%
SLR HC FUND SPV, LLC	$33,608,295.01	14.94%
SLR HC BDC LLC	$7,074,049.92	3.14%
TOTAL	**$225,000,000.00**	**100.00%**

SCHEDULE 7.13

Minimum Net Product Revenue

[to be attached]

Month	Trailing 12 Months Minimum Net Product Revenue	
Dec-2023	$	30,000,000

Month	Trailing 6 Months Minimum Net Product Revenue	
Jan-2024	$	24,000,000
Feb-2024	$	26,000,000
Mar-2024	$	28,000,000
Apr-2024	$	30,000,000
May-2024	$	32,000,000
Jun-2024	$	34,000,000
Jul-2024	$	36,000,000
Aug-2024	$	38,000,000
Sep-2024	$	40,000,000
Oct-2024	$	42,000,000
Nov-2024	$	44,000,000
Dec-2024	$	46,000,000
Jan-2025	$	47,000,000
Feb-2025	$	49,000,000
Mar-2025	$	50,000,000
Apr-2025	$	53,000,000
May-2025	$	55,000,000
Jun-2025	$	59,000,000
Jul-2025	$	64,000,000
Aug-2025	$	68,000,000
Sep-2025	$	73,000,000
Oct-2025	$	78,000,000
Nov-2025	$	83,000,000
Dec-2025	$	87,000,000
Jan-2026	$	92,000,000
Feb-2026	$	97,000,000
Mar-2026	$	101,000,000
Apr-2026	$	105,000,000
May-2026	$	108,000,000
Jun-2026	$	110,000,000
Jul-2026	$	110,000,000
Aug-2026	$	110,000,000
Sep-2026	$	110,000,000
Oct-2026	$	110,000,000
Nov-2026	$	110,000,000
Dec-2026	$	110,000,000

EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (a) more than 65% of the presently existing and hereafter arising issued and outstanding equity interests owned by Borrower of any Excluded Subsidiary which equity interests entitle the holder thereof to vote for directors or any other matter (provided, however, that immediately upon any change in the U.S. tax laws that would allow the pledge of a greater percentage of such voting equity interests without material adverse tax consequences to Borrower, the Collateral shall automatically and without further action required by, and without notice to, any Person include such greater percentage of voting equity interests of such Excluded Subsidiary from that time forward), (b) any interest of Borrower as a lessee or sublessee under a real property lease; (c) rights held under a license or other agreement that are not assignable by their terms without the consent of the counterparty thereof (but only to the extent such restriction on assignment is effective under Section 9-406, 9-407, 9-408 or 9-409 of the Code (or any successor provision or provisions) of any relevant jurisdiction or any other applicable law (including the Bankruptcy Code) or principles of equity); or (d) any interest of Borrower as a lessee or borrower under an Equipment lease or Equipment financing if Borrower is prohibited by the terms of such agreement from granting a security interest in such lease or agreement or under which such an assignment or Lien would cause a default to occur under such lease; provided, however, that upon termination of such prohibition, such interest shall immediately become Collateral without any action by Borrower, Collateral Agent or any Lender.

EXHIBIT B

Collateral Agent and Lender Terms

1. Appointment of Collateral Agent.

(a) Each Lender hereby appoints SLR (together with any successor Collateral Agent pursuant to Section 7 of this Exhibit B) as Collateral Agent under the Loan Documents and authorizes Collateral Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from Borrower, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Collateral Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto.

(b) Without limiting the generality of clause (a) above, Collateral Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Lender is hereby authorized to make such payment to Collateral Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of Collateral Agent and Lenders with respect to any Obligation in any bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Lender), (iii) act as collateral agent for the Secured Parties for purposes of the perfection of all Liens created by the Loan Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral as permitted pursuant to the Loan Agreement, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, exercise all remedies given to Collateral Agent and the other Lenders with respect to the Borrower and/or the Collateral, whether under the Loan Documents, applicable Requirements of Law or otherwise and (vii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; provided, however, that Collateral Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Collateral Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any Deposit Account maintained by Borrower or any Guarantor with, and cash and Cash Equivalents held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to Collateral Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed. Collateral Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Lender). Any such Person shall benefit from this Exhibit B to the extent provided by Collateral Agent.

(c) Under the Loan Documents, and except as expressly set forth in this Exhibit B, Collateral Agent (i) is acting solely on behalf of the Lenders, with duties that are entirely administrative in nature, notwithstanding the use of the defined term "Collateral Agent", the terms "agent", "Collateral Agent" and "collateral agent" and similar terms in any Loan Document to refer to Collateral Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Person and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document, and each Lender, by accepting the benefits of the Loan Documents, hereby waives and agrees not to assert any claim against Collateral Agent based on the roles, duties and legal relationships expressly disclaimed in clauses (i) through (iii) above. Except as expressly set forth in the Loan Documents, Collateral Agent shall not have any duty to disclose, and shall not be liable for failure to disclose, any information relating to Borrower or any of its Subsidiaries that is communicated to or obtained by SLR or any of its Affiliates in any capacity.

2. Binding Effect; Use of Discretion; E-Systems.

(a) Each Lender, by accepting the benefits of the Loan Documents, agrees that (i) any action taken by Collateral Agent or the Required Lenders (or, if expressly required in any Loan Document, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Collateral Agent in reliance upon the instructions of the Required Lenders (or, where so required, such greater proportion) and (iii) the exercise by Collateral Agent or the Required Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of Lenders.

(b) If Collateral Agent shall request instructions from the Required Lenders or all affected Lenders with respect to any act or action (including failure to act) in connection with any Loan Document, then Collateral Agent shall be entitled to refrain from such act or taking such action unless and until Collateral Agent shall have received instructions from the Required Lenders or all affected Lenders, as the case may be, and Collateral Agent shall not incur liability to any Person by reason of so refraining. Collateral Agent shall be fully justified in failing or refusing to take any action under any Loan Document (i) if such action would, in the opinion of Collateral Agent, be contrary to any Requirement of Law or any Loan Document, (ii) if such action would, in the opinion of Collateral Agent, expose Collateral Agent to any potential liability under any Requirement of Law or (iii) if Collateral Agent shall not first be indemnified to its satisfaction against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. Without limiting the foregoing, no Lender shall have any right of action whatsoever against Collateral Agent as a result of Collateral Agent acting or refraining from acting under any Loan Document in accordance with the instructions of the Required Lenders or all affected Lenders, as applicable.

(c) Collateral Agent is hereby authorized by Borrower and each Lender to establish procedures (and to amend such procedures from time to time) to facilitate administration and servicing of the Term Loans and other matters incidental thereto. Without limiting the generality of the foregoing, Collateral Agent is hereby authorized to establish procedures to make available or deliver, or to accept, notices, documents (including, without limitation, borrowing base certificates) and similar items on, by posting to or submitting and/or completion, on E-Systems. Borrower and each Lender acknowledges and agrees that the use of transmissions via an E-System or electronic mail is not necessarily secure and that there are risks associated with such use, including risks of interception, disclosure and abuse, and Borrower and each Lender assumes and accepts such risks by hereby authorizing the transmission via E-Systems or electronic mail. Each "e-signature" on any such posting shall be deemed sufficient to satisfy any requirement for a "signature", and each such posting shall be deemed sufficient to satisfy any requirement for a "writing", in each case including pursuant to any Loan Document, any applicable provision of any Code, the federal Uniform Electronic Transactions Act, the Electronic Signatures in Global and National Commerce Act and any substantive or procedural Requirement of Law governing such subject matter. All uses of an E-System shall be governed by and subject to, in addition to this Section, the separate terms, conditions and privacy policy posted or referenced in such E-System (or such terms, conditions and privacy policy as may be updated from time to time, including on such E-System) and related contractual obligations executed by Collateral Agent, Borrower and/or Lenders in connection with the use of such E-System. ALL E-SYSTEMS AND ELECTRONIC TRANSMISSIONS SHALL BE PROVIDED "AS IS" AND "AS AVAILABLE". NO REPRESENTATION OR WARRANTY OF ANY KIND IS MADE BY AGENT, ANY LENDER OR ANY OF THEIR RELATED PERSONS IN CONNECTION WITH ANY E-SYSTEMS.

3. Collateral Agent's Reliance, Etc. Collateral Agent may, without incurring any liability hereunder, (a) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, Borrower) and (b) rely and act upon any document and information (including those transmitted by electronic transmission) and any telephone message or conversation, in each case believed by it in good faith to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. None of Collateral Agent and its Related Persons shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and Borrower hereby waives and shall not assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting from the gross

negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment of a court of competent jurisdiction) in connection with the duties of Collateral Agent expressly set forth herein. Without limiting the foregoing, Collateral Agent: (i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Required Lenders or for the actions or omissions of any of its Related Persons, except to the extent that a court of competent jurisdiction determines in a final non-appealable judgment that Collateral Agent acted with gross negligence or willful misconduct in the selection of such Related Person; (ii) shall not be responsible to any Lender or other Person for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document; (iii) makes no warranty or representation, and shall not be responsible, to any Lender or other Person for any statement, document, information, representation or warranty made or furnished by or on behalf of Borrower or any Related Person of Borrower in connection with any Loan Document or any transaction contemplated therein or any other document or information with respect to Borrower, whether or not transmitted or (except for documents expressly required under any Loan Document to be transmitted to the Lenders) omitted to be transmitted by Collateral Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Collateral Agent in connection with the Loan Documents; and (iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of Borrower or as to the existence or continuation or possible occurrence or continuation of any Event of Default, and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from Borrower or any Lender describing such Event of Default that is clearly labelled "notice of default" (in which case Collateral Agent shall promptly give notice of such receipt to all Lenders, provided that Collateral Agent shall not be liable to any Lender for any failure to do so, except to the extent that such failure is attributable to Collateral Agent's gross negligence or willful misconduct as determined by a final non-appealable judgment of a court of competent jurisdiction); and, for each of the items set forth in clauses (i) through (iv) above, each Lender and Borrower hereby waives and agrees not to assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action it might have against Collateral Agent based thereon.

4. Collateral Agent Individually. Collateral Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, engage in any kind of business with, Borrower or any Affiliate of Borrower as though it were not acting as Collateral Agent and may receive separate fees and other payments therefor. To the extent Collateral Agent or any of its Affiliates makes any Term Loans or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Required Lender" and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, Collateral Agent or such Affiliate, as the case may be, in its individual capacity as Lender, or as one of the Required Lenders.

5. Lender Credit Decision; Collateral Agent Report. Each Lender acknowledges that it shall, independently and without reliance upon Collateral Agent, any Lender or any of their Related Persons or upon any document solely or in part because such document was transmitted by Collateral Agent or any of its Related Persons, conduct its own independent investigation of the financial condition and affairs of Borrower and make and continue to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate. Except for documents expressly required by any Loan Document to be transmitted by Collateral Agent to the Lenders, Collateral Agent shall not have any duty or responsibility to provide any Lender with any credit or other information concerning the business, prospects, operations, Property, financial and other condition or creditworthiness of Borrower or any Affiliate of Borrower that may come in to the possession of Collateral Agent or any of its Related Persons. Each Lender agrees that is shall not rely on any field examination, audit or other report provided by Collateral Agent or its Related Persons (an "**Collateral Agent Report**"). Each Lender further acknowledges that any Collateral Agent Report (a) is provided to the Lenders solely as a courtesy, without consideration, and based upon the understanding that such Lender will not rely on such Collateral Agent Report, (b) was prepared by Collateral Agent or its Related Persons based upon information provided by Borrower solely for Collateral Agent's own internal use, and (c) may not be complete and may not reflect all information and

findings obtained by Collateral Agent or its Related Persons regarding the operations and condition of Borrower. Neither Collateral Agent nor any of its Related Persons makes any representations or warranties of any kind with respect to (i) any existing or proposed financing, (ii) the accuracy or completeness of the information contained in any Collateral Agent Report or in any related documentation, (iii) the scope or adequacy of Collateral Agent's and its Related Persons' due diligence, or the presence or absence of any errors or omissions contained in any Collateral Agent Report or in any related documentation, and (iv) any work performed by Collateral Agent or Collateral Agent's Related Persons in connection with or using any Collateral Agent Report or any related documentation. Neither Collateral Agent nor any of its Related Persons shall have any duties or obligations in connection with or as a result of any Lender receiving a copy of any Collateral Agent Report. Without limiting the generality of the forgoing, neither Collateral Agent nor any of its Related Persons shall have any responsibility for the accuracy or completeness of any Collateral Agent Report, or the appropriateness of any Collateral Agent Report for any Lender's purposes, and shall have no duty or responsibility to correct or update any Collateral Agent Report or disclose to any Lender any other information not embodied in any Collateral Agent Report, including any supplemental information obtained after the date of any Collateral Agent Report. Each Lender releases, and agrees that it will not assert, any claim against Collateral Agent or its Related Persons that in any way relates to any Collateral Agent Report or arises out of any Lender having access to any Collateral Agent Report or any discussion of its contents, and agrees to indemnify and hold harmless Collateral Agent and its Related Persons from all claims, liabilities and expenses relating to a breach by any Lender arising out of such Lender's access to any Collateral Agent Report or any discussion of its contents.

6. Indemnification. Each Lender agrees to reimburse Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents (including pursuant to Section 12.2 of the Agreement)) promptly upon demand for its Pro Rata Share of any out-of-pocket costs and expenses (including, without limitation, fees, charges and disbursements of financial, legal and other advisors and any Taxes or insurance paid in the name of, or on behalf of, Borrower) incurred by Collateral Agent or any of its Related Persons in connection with the preparation, syndication, execution, delivery, administration, modification, amendment, consent, waiver or enforcement of, or the taking of any other action (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding (including, without limitation, preparation for and/or response to any subpoena or request for document production relating thereto) or otherwise) in respect of, or legal advice with respect to, its rights or responsibilities under, any Loan Document. Each Lender further agrees to indemnify Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents (including pursuant to Section 12.2 of the Agreement)), ratably according to its Pro Rata Share, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever (including, to the extent not indemnified by the applicable Lender, Taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to or for the account of any Lender) that may be imposed on, incurred by, or asserted against Collateral Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Collateral Agent or any of its Related Persons under or with respect to the foregoing; provided that no Lender shall be liable to Collateral Agent or any of its Related Persons under this Section 6 of this Exhibit B to the extent such liability has resulted from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person, as determined by a final non-appealable judgment of a court of competent jurisdiction. To the extent required by any applicable Requirement of Law, Collateral Agent may withhold from any payment to any Lender under a Loan Document an amount equal to any applicable withholding Tax. If the IRS or any other Governmental Authority asserts a claim that Collateral Agent did not properly withhold Tax from amounts paid to or for the account of any Lender for any reason, or if Collateral Agent reasonably determines that it was required to withhold Taxes from a prior payment to or for the account of any Lender but failed to do so, such Lender shall promptly indemnify Collateral Agent fully for all amounts paid, directly or indirectly, by Collateral Agent as Tax or otherwise, including penalties and interest, and together with all expenses incurred by Collateral Agent. Collateral Agent may offset against any payment to any Lender under a Loan Document, any applicable withholding Tax that was required to be withheld from any prior payment to such Lender but which was not so withheld, as well as any other amounts for which Collateral Agent is entitled to indemnification from such Lender under the immediately preceding sentence of this Section 6 of this Exhibit B.

7. Successor Collateral Agent. Collateral Agent may resign at any time by delivering notice of such resignation to the Lenders and Borrower, effective on the date set forth in such notice or, if no such date is set forth therein, upon the date such notice shall be effective, in accordance with the terms of this Section 7 of this Exhibit B. If Collateral Agent delivers any such notice, the Required Lenders shall have the right to appoint a successor Collateral Agent. If, after thirty (30) days after the date of the retiring Collateral Agent's notice of resignation, no successor Collateral Agent has been appointed by the Required Lenders and has accepted such appointment, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent from among the Lenders. Effective immediately upon its resignation, (a) the retiring Collateral Agent shall be discharged from its duties and obligations under the Loan Documents, (b) the Lenders shall assume and perform all of the duties of Collateral Agent until a successor Collateral Agent shall have accepted a valid appointment hereunder, (c) the retiring Collateral Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to any actions taken or omitted to be taken while such retiring Collateral Agent was, or because such Collateral Agent had been, validly acting as Collateral Agent under the Loan Documents, and (iv) subject to its rights under Section 2(b) of this Exhibit B, the retiring Collateral Agent shall take such action as may be reasonably necessary to assign to the successor Collateral Agent its rights as Collateral Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Collateral Agent, a successor Collateral Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the retiring Collateral Agent under the Loan Documents.

8. Release of Collateral. Each Lender hereby consents to the release and hereby directs Collateral Agent to release (or in the case of clause (b)(ii) below, release or subordinate) the following:

(a) any Guarantor if all of the stock of such Subsidiary owned by Borrower is sold or transferred in a transaction permitted under the Loan Documents (including pursuant to a valid waiver or consent), to the extent that, after giving effect to such transaction, such Subsidiary would not be required to guaranty any Obligations pursuant to any Loan Document; and

(b) any Lien held by Collateral Agent for the benefit of the Secured Parties against (i) any Collateral that is sold or otherwise disposed of by Borrower in a transaction permitted by the Loan Documents (including pursuant to a valid waiver or consent), (ii) any Collateral subject to a Lien that is expressly permitted under clause (c) of the definition of the term "Permitted Lien" and (iii) all of the Collateral and Borrower, upon (A) termination of all of the Commitments, (B) the payment in full in cash of all of the Obligations (other than (a)(i) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made, and (b) all obligations under the Exit Fee Agreement), and (C) to the extent requested by Collateral Agent, receipt by Collateral Agent and Lenders of liability releases from Borrower in form and substance acceptable to Collateral Agent (the satisfaction of the conditions in this clause (iii), the "**Termination Date**").

9. Setoff and Sharing of Payments. In addition to any rights now or hereafter granted under any applicable Requirement of Law and not by way of limitation of any such rights, upon the occurrence and during the continuance of any Event of Default and subject to Section 10(d) of this Exhibit B, each Lender is hereby authorized at any time or from time to time upon the direction of Collateral Agent, without notice to Borrower or any other Person, any such notice being hereby expressly waived, to setoff and to appropriate and to apply any and all balances held by it at any of its offices for the account of Borrower (regardless of whether such balances are then due to Borrower) and any other properties or assets at any time held or owing by that Lender or that holder to or for the credit or for the account of Borrower against and on account of any of the Obligations that are not paid when due. Any Lender exercising a right of setoff or otherwise receiving any payment on account of the Obligations in excess of its Pro Rata Share thereof shall purchase for cash (and the other Lenders or holders shall sell) such participations in each such other Lender's or holder's Pro Rata Share of the Obligations as would be necessary to cause such Lender to share the amount so offset or otherwise received with each other Lender or holder in accordance with their respective Pro Rata Shares of the Obligations. Borrower agrees, to the fullest extent permitted by law, that (a) any Lender may exercise its right to offset with respect to amounts in excess of its Pro Rata Share of the Obligations and may purchase participations in accordance with the preceding sentence and (b) any Lender so purchasing a participation in the Term Loans made or other Obligations held by other Lenders or holders may exercise all rights of offset,

bankers' liens, counterclaims or similar rights with respect to such participation as fully as if such Lender or holder were a direct holder of the Term Loans and the other Obligations in the amount of such participation. Notwithstanding the foregoing, if all or any portion of the offset amount or payment otherwise received is thereafter recovered from the Lender that has exercised the right of offset, the purchase of participations by that Lender shall be rescinded and the purchase price restored without interest.

10. Advances; Payments; Non-Funding Lenders; Actions in Concert.

(a) Advances; Payments. If Collateral Agent receives any payment with respect to a Term Loan for the account of the Lenders on or prior to 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on such Business Day. If Collateral Agent receives any payment with respect to a Term Loan for the account of Lenders after 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on the next Business Day.

(b) Return of Payments.

(i) If Collateral Agent pays an amount to a Lender under this Agreement in the belief or expectation that a related payment has been or will be received by Collateral Agent or on behalf of from Borrower and such related payment is not received by Collateral Agent, then Collateral Agent will be entitled to recover such amount (including interest accruing on such amount at the rate otherwise applicable to such Obligation) from such Lender on demand without setoff, counterclaim or deduction of any kind.

(ii) If Collateral Agent determines at any time that any amount received by Collateral Agent under any Loan Document must be returned to Borrower or paid to any other Person pursuant to any insolvency law or otherwise, then, notwithstanding any other term or condition of any Loan Document, Collateral Agent will not be required to distribute any portion thereof to any Lender. In addition, each Lender will repay to Collateral Agent on demand any portion of such amount that Collateral Agent has distributed to such Lender, together with interest at such rate, if any, as Collateral Agent is required to pay to Borrower or such other Person, without setoff, counterclaim or deduction of any kind and Collateral Agent will be entitled to set off against future distributions to such Lender any such amounts (with interest) that are not repaid on demand.

(c) Non-Funding Lenders.

(i) Unless Collateral Agent shall have received notice from a Lender prior to the date of any Term Loan that such Lender will not make available to Collateral Agent such Lender's Pro Rata Share of such Term Loan, Collateral Agent may assume that such Lender will make such amount available to it on the date of such Term Loan in accordance with Section 2(b) of this Exhibit B, and Collateral Agent may (but shall not be obligated to), in reliance upon such assumption, make available a corresponding amount for the account of Borrower on such date. If and to the extent that such Lender shall not have made such amount available to Collateral Agent, such Lender and Borrower severally agree to repay to Collateral Agent forthwith on demand such corresponding amount together with interest thereon, for each day from the day such amount is made available to Borrower until the day such amount is repaid to Collateral Agent, at a rate per annum equal to the interest rate applicable to the Obligation that would have been created when Collateral Agent made available such amount to Borrower had such Lender made a corresponding payment available. If such Lender shall repay such corresponding amount to Collateral Agent, the amount so repaid shall constitute such Lender's portion of such Term Loan for purposes of this Agreement.

(ii) To the extent that any Lender has failed to fund any Term Loan or any other payments required to be made by it under the Loan Documents after any such Term Loan is required to be made or such payment is due (a "**Non-Funding Lender**"), Collateral Agent shall be entitled to set off the funding short-fall against that Non-Funding Lender's Pro Rata Share of all payments received from or on behalf of Borrower thereunder. The failure of any Non-Funding Lender to make any Term Loan or any payment required by it hereunder shall not relieve any other Lender (each such other Lender, an "**Other Lender**") of its obligations to make such Term Loan, but neither any Other Lender

nor Collateral Agent shall be responsible for the failure of any Non-Funding Lender to make such Term Loan or make any other payment required hereunder. Notwithstanding anything set forth herein to the contrary, a Non-Funding Lender shall not have any voting or consent rights under or with respect to any Loan Document or constitute a "Lender" (or be included in the calculation of "Required Lenders" hereunder) for any voting or consent rights under or with respect to any Loan Document. At Borrower's request, Collateral Agent or a Person reasonably acceptable to Collateral Agent shall have the right with Collateral Agent's consent and in Collateral Agent's sole discretion (but Collateral Agent or any such Person shall have no obligation) to purchase from any Non-Funding Lender, and each Lender agrees that if it becomes a Non-Funding Lender it shall, at Collateral Agent's request, sell and assign to Collateral Agent or such Person, all of the Term Loan Commitment (if any), and all of the outstanding Term Loan of that Non-Funding Lender for an amount equal to the aggregate outstanding principal balance of the Term Loan held by such Non-Funding Lender and all accrued interest with respect thereto through the date of sale, such purchase and sale to be consummated pursuant to an executed assignment agreement in form and substance reasonably satisfactory to, and acknowledged by, Collateral Agent.

(d) Actions in Concert. Anything in this Agreement to the contrary notwithstanding, each Lender hereby agrees with each other Lender that no Lender shall take any action to protect or enforce its rights arising out of any Loan Document (including exercising any rights of setoff) without first obtaining the prior written consent of Collateral Agent or Required Lenders, it being the intent of Lenders that any such action to protect or enforce rights under any Loan Document shall be taken in concert and at the direction or with the consent of Collateral Agent or Required Lenders.

EXHIBIT C

[Taxes; Increased Costs.]

1. Defined Terms. For purposes of this Exhibit C:

(a) "**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

(b) "**Excluded Taxes**" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient, (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (A) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (B) that are Other Connection Taxes, (ii) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Term Loan or Term Loan Commitment pursuant to a law in effect on the date on which (A) such Lender acquires such interest in the Term Loan or Term Commitment or (B) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2 or Section 4 of this Exhibit C, amounts with respect to such Taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (iii) Taxes attributable to such Recipient's failure to comply with Section 7 of this Exhibit C and (iv) any withholding Taxes imposed under FATCA.

(c) "**FATCA**" means Sections 1471 through 1474 of the Internal Revenue Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code, and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Internal Revenue Code.

(d) "**Foreign Lender**" means a Lender that is not a U.S. Person.

(e) "**Indemnified Taxes**" means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (ii) to the extent not otherwise described in clause (i), Other Taxes.

(f) "**Other Connection Taxes**" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Term Loan or Loan Document).

(g) "**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

(h) "**Recipient**" means Collateral Agent or any Lender, as applicable.

(i) "**U.S. Person**" means any Person that is a "United States person" as defined in Section 7701(a)(30) of the Internal Revenue Code.

(j) "**Withholding Agent**" means Borrower and Collateral Agent.

2. Payments Free of Taxes. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld

to the relevant Governmental Authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2 or Section 4 of this Exhibit C) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

3. Payment of Other Taxes by Borrower. Borrower shall timely pay to the relevant Governmental Authority in accordance with applicable law, or at the option of Collateral Agent timely reimburse it for the payment of, any Other Taxes.

4. Indemnification by Borrower. Borrower shall indemnify each Recipient, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under Section 2 of this Exhibit C or this Section 4) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Borrower by a Lender (with a copy to Collateral Agent), or by Collateral Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error.

5. Indemnification by the Lenders. Each Lender shall severally indemnify Collateral Agent, within ten (10) days after demand therefor, for (a) any Indemnified Taxes attributable to such Lender (but only to the extent that Borrower has not already indemnified Collateral Agent for such Indemnified Taxes and without limiting the obligation of Borrower to do so), (b) any Taxes attributable to such Lender's failure to comply with the provisions of Section 12.1 of the Agreement relating to the maintenance of a Participant Register and (c) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by Collateral Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by Collateral Agent shall be conclusive absent manifest error. Each Lender hereby authorizes Collateral Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by Collateral Agent to the Lender from any other source against any amount due to Collateral Agent under this Section 5.

6. Evidence of Payments. As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to the provisions of this Exhibit C, Borrower shall deliver to Collateral Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Collateral Agent.

7. Status of Lenders.

(a) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower and Collateral Agent, at the time or times reasonably requested by Borrower or Collateral Agent, such properly completed and executed documentation reasonably requested by Borrower or Collateral Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by Borrower or Collateral Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower or Collateral Agent as will enable Borrower or Collateral Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Sections 7(b)(i), 7(b)(ii) and 7(b)(iv) of this Exhibit C) shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

(b) Without limiting the generality of the foregoing, in the event that Borrower is a U.S. Person,

(i) any Lender that is a U.S. Person shall deliver to Borrower and Collateral Agent on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Collateral Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax;

(ii) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Collateral Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Collateral Agent), whichever of the following is applicable:

(A) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(B) executed copies of IRS Form W-8ECI;

(C) in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Internal Revenue Code, (x) a certificate, in form and substance reasonably acceptable to Borrower and Collateral Agent, to the effect that such Foreign Lender (or other applicable Person) is not a "bank" within the meaning of Section 881(c)(3)(A) of the Internal Revenue Code, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the Internal Revenue Code, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the Internal Revenue Code (a "**U.S. Tax Compliance Certificate**") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or

(D) to the extent a Foreign Lender is not the beneficial owner, executed copies of IRS Form W-8IMY, accompanied by IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate, IRS Form W-9, and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate on behalf of each such direct and indirect partner;

(iii) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Collateral Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Collateral Agent), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower or Collateral Agent to determine the withholding or deduction required to be made; and

(iv) if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Internal Revenue Code, as applicable), such Lender shall deliver to Borrower and Collateral Agent at the time or times prescribed by law and at such time or times reasonably requested by Borrower or Collateral Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Internal Revenue Code) and such additional documentation reasonably requested by Borrower or Collateral Agent as may be necessary for Borrower and Collateral Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(v) Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower and Collateral Agent in writing of its legal inability to do so.

8. Treatment of Certain Refunds. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to the provisions of this Exhibit C

(including by the payment of additional amounts pursuant to the provisions of this Exhibit C), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under the provisions of this Exhibit C with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 8 (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this Section 8, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 8 the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This Section 8 shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

9. Increased Costs. If any change in applicable law shall subject any Recipient to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (ii) through (iv) of the definition of Excluded Taxes and (C) Connection Income Taxes) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, and the result shall be to increase the cost to such Recipient of making, converting to, continuing or maintaining any Term Loan or of maintaining its obligation to make any such Term Loan, or to reduce the amount of any sum received or receivable by such Recipient (whether of principal, interest or any other amount), then, upon the request of such Recipient, Borrower will pay to such Recipient such additional amount or amounts as will compensate such Recipient for such additional costs incurred or reduction suffered.

10. Survival. Each party's obligations under the provisions of this Exhibit C shall survive the resignation or replacement of Collateral Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Term Loan Commitments and the repayment, satisfaction or discharge of all obligations under any Loan Document.

EXHIBIT D

Loan Payment Request Form

Fax To: (212) 993-1698 Date: _____

Loan Payment:
ARCUTIS BIOTHERAPEUTICS, INC.

From Account #_____ To Account #_____
(Deposit Account #) (Loan Account #)
Principal $_____and/or Interest
$_____

Authorized Signature: Phone Number:
Print Name/Title:

Loan Advance:

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account #_____ To Account #_____
(Loan Account #) (Deposit Account #)

Amount of Advance $_____

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date:

Authorized Signature**:** Phone Number:
Print Name/Title**:**

Outgoing Wire Request:

Complete only if all or a portion of funds from the loan advance above is to be wired.

Beneficiary Name: _____ Amount of Wire: $
Beneficiary Bank: _____ Account Number:
City and State:

Beneficiary Bank Transit (ABA) #: Beneficiary Bank Code (Swift, Sort, Chip, etc.):
(For International Wire Only)
Intermediary Bank: Transit (ABA) #:
For Further Credit to:

Special Instruction:
By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: _____ 2nd Signature (if required): _____
Print Name/Title: _____ Print Name/Title: _____
Telephone #: Telephone #:

EXHIBIT E

Compliance Certificate

TO: SLR INVESTMENT CORP., as Collateral Agent and Lender
and the Lenders listed on Schedule 1.1 of the Loan Agreement

FROM: ARCUTIS BIOTHERAPEUTICS, INC.

The undersigned authorized officer ("**Officer**") of ARCUTIS BIOTHERAPEUTICS, INC. ("**Borrower**"), hereby certifies solely in his/her capacity as an officer of Borrower and not in his/her individual capacity, that in accordance with the terms and conditions of the Loan and Security Agreement dated as of December 22, 2021, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "**Loan Agreement**;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below;

(b) There are no Default or Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports; Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local Taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are [prepared in accordance with Generally Accepted Accounting Principles (GAAP)][1] and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

[1] Insert for annual and quarterly financial statements only.

	Reporting Covenant	Requirement	Actual	Complies		
1)	Monthly financial statements	Monthly within 30 days		Yes	No	N/A
2)	Quarterly financial statements	Quarterly within 45 days		Yes	No	N/A
3)	Annual (CPA Audited) statements	Within 90 days after FYE or 5 days after filing with SEC		Yes	No	N/A
4)	Annual Financial Projections/ Budget	Annually (within earlier 10 days of approval or Feb 28th of each year), and when revised		Yes	No	N/A
5)	A/R & A/P agings	If applicable		Yes	No	N/A
7)	Compliance Certificate	Monthly within 30 days		Yes	No	N/A
8)	IP notice (events reasonably expected to materially and adversely affect value of IP or result in MAC)	When required		Yes	No	N/A
9)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		$_____	Yes	No	N/A
10)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		$_____	Yes	No	N/A

Deposit and Securities Accounts
(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?		Account Control Agreement in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

Financial Covenants

Minimum Net Product Revenue (period ending _____)	Actual Net Product Revenue $_____	Minimum Net Product Revenue per Section 7.15 $_____	Complies		
			Yes	No	N/A

Other Matters

1)	Have there been any changes in Key Persons since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than One Million Dollars ($1,000,000.00)?	Yes	No
4)	Have there been any amendments or changes to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No
5)	Has Borrower or any Subsidiary entered into or amended and Material Agreement? If yes, please explain and provide a copy of the Material Agreement(s) and/or amendment(s)	Yes	No
6)	Has Borrower provided the Collateral Agent with all notices required to be delivered under Sections 6.2(a) and 6.2(b) of the Loan Agreement?	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

ARCUTIS BIOTHERAPEUTICS, INC.

By: _____
Name: _____
Title: _____

Date:

COLLATERAL AGENT USE ONLY

Received by:_____ Date: _____

Verified by: _____ Date: _____

Compliance Status: Yes No

EXHIBIT F

CORPORATE BORROWING CERTIFICATE

Borrower: ARCUTIS BIOTHERAPEUTICS, INC. **Date**: December 22, 2021

Lenders: SLR INVESTMENT CORP., as Collateral Agent and Lender and the and the Lenders listed on Schedule 1.1 of the Loan Agreement

I hereby certify, solely in my capacity as an officer of Borrower and not in my individual capacity, as follows, as of the date set forth above:

1. I am the Chief Financial Officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's board of directors (or a duly authorized committee thereof) at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[*Balance of Page Intentionally Left Blank*]

Resolved, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories
			☐
			☐
			☐
			☐

Resolved Further, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

Resolved Further, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

Execute Loan Documents. Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets, other than any excluded assets pursuant to the last paragraph of Exhibit A to the Loan Agreement.

Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

Pay Fees. Pay fees under the Loan Agreement or any other Loan Document.

Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

Resolved Further, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[*Balance of Page Intentionally Left Blank*]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By:

Name: Scott Burrows

Title: Chief Financial Officer

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the President and CEO of Borrower, solely in my capacity as an officer of Borrower and not in my individual capacity, as to paragraphs 1 through 5 above, as of the date set forth above.

By:

Name: Todd Franklin Watanabe

Title: President and CEO

Exhibit A

Certificate of Incorporation (including amendments)

Exhibit B

Bylaws

EXHIBIT G

ACH LETTER

SLR INVESTMENT CORP.
500 Park Avenue, 3rd Floor
New York, NY 10022
Attention:
Fax:
Email:

Re: Loan and Security Agreement dated as of December 22, 2021 (the "Agreement") by and among ARCUTIS BIOTHERAPEUTICS, INC. ("Borrower"), SLR Investment Corp. ("SLR"), as collateral agent (in such capacity, "Collateral Agent") and the Lenders listed on Schedule 1.1 thereof or otherwise a party thereto from time to time, including SLR in its capacity as a Lender (each a "Lender" and collectively, the "Lenders"). Capitalized terms used but not otherwise defined herein shall have the meanings given them under the Agreement.

In connection with the above referenced Agreement, the Borrower hereby authorizes the Collateral Agent to, at its discretion and with prior notice of at least one (1) Business Day, initiate debit entries to the Borrower's account indicated below (i) on each payment date of all Obligations then due and owing, (ii) at any time any payment due and owing with respect to Lender Expenses, and (iii) upon an Event of Default, any other Obligations outstanding, in each case pursuant to Section 2.3(e) of the Agreement. The Borrower authorizes the depository institution named below to debit to such account.

DEPOSITORY NAME	BRANCH
CITY	STATE AND ZIP CODE
TRANSIT/ABA NUMBER	ACCOUNT NUMBER

This authority will remain in full force and effect so long as any amounts are due under the Agreement.

ARCUTIS BIOTHERAPEUTICS, INC.

By: _____

Title: _____

Date:_____

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-252612) of Arcutis Biotherapeutics, Inc.,
(2) Registration Statement (Form S-8 No. 333-236178) pertaining to the 2017 Equity Incentive Plan, the 2020 Equity Incentive Plan, and the 2020 Employee Stock Purchase Plan of Arcutis Biotherapeutics, Inc., and
(3) Registration Statement (Form S-8 No. 333-253155) pertaining to securities to be offered to employees in employee benefit plans of Arcutis Biotherapeutics, Inc.,

of our reports dated February 22, 2022, with respect to the financial statements of Arcutis Biotherapeutics, Inc., and the effectiveness of internal control over financing reporting of Arcutis Biotherapeutics, Inc., included in this Annual Report (Form 10-K) of Arcutis Biotherapeutics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Los Angeles, California
February 22, 2022

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 Annual Report on Form 10-K 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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;

    (c) 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

    (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: February 22, 2022

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 Annual Report on Form 10-K 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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;

    (c) 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

    (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: February 22, 2022

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 Annual Report of Arcutis Biotherapeutics, Inc. (the "Company") on Form 10-K for the period ended December 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: February 22, 2022 By: /s/ Todd Franklin Watanabe

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

Date: February 22, 2022 By: /s/ Scott L. Burrows

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

Corporate and Stockholder Information

Management

Frank Watanabe
President and CEO

David Osborne, Ph.D.
Chief Technical Officer

Patrick Burnett, M.D., Ph.D., FAAD
Chief Medical Officer

Scott Burrows
Chief Financial Officer

Ken Lock
Chief Commercial Officer

Raj Madan
Chief Digital and Information Officer

Mas Matsuda, J.D.
General Counsel & Corporate Secretary

Matthew Moore
Chief Business Officer

Patricia Turney
Senior Vice President, Operations

Corporate Headquarters

Arcutis Biotherapeutics, Inc.
3027 Townsgate Road, Suite #300
Westlake Village, CA 91361
www.arcutis.com

Transfer Agent

Equiniti Trust Company
PO Box 64854
St Paul MN 55164-0854
1.800.468.9716

Independent Registered Accounting Firm

Ernst & Young LLP
Los Angeles, California

ARCUTIS
BIOTHERAPEUTICS

Market Information

Our common stock is listed on The Nasdaq Global Select Market under the ticker symbol ARQT.

Copies of our Form 10-K and proxy statement filed with the Securities and Exchange Commission and other information pertinent to our investors, including contact information for investor relations inquiries, are available free of charge on our website at **https://investors.arcutis.com/**

This document contains "forward-looking" statements. These statements involve substantial known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements and you should not place undue reliance on our forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in the clinical development process and regulatory approval process, the timing of regulatory filings, and our ability to defend our intellectual property. For a further description of the risks and uncertainties applicable to our business, see the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, as well as any subsequent filings with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

3027 Townsgate Road, Suite 300
Westlake Village, CA 91361

Corporate contact:
information@arcutis.com
805-418-5006

Media and investor contact:
ir@arcutis.com

For more information, visit www.arcutis.com

Arcutis Biotherapeutics, Inc.

@ArcutisBio