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, 2020
OR

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

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-2974255**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
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 ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $619,916,280 as of June 30, 2020.

The number of shares of the registrant’s Common Stock outstanding as of February 11, 2021 was 50,084,677.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant’s Proxy Statement for the registrant’s 2021 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, 2020.

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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. 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, topical 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 for roflumilast cream, roflumilast foam, ARQ-252 and ARQ-255;
- future agreements, if any, with third parties in connection with the commercialization of our product candidates;
- the success, cost and timing of our product candidate development activities and planned clinical trials;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the potential market size and the size of the patient populations for our product candidates, if approved for commercial uses;
- the potential US 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 Securities and Exchange Commission 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 II 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;
- Our business is dependent on the development, regulatory approval and commercialization of our current product candidates;
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates;
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations;
- Interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- Certain of the endpoints in our planned clinical trials rely on a subjective assessment of the effect of the product candidate in the subject by either the physician or patient, and may prove difficult to meet in patients with more severe disease, which exposes us to a variety of risks for the successful completion of our clinical trials;
- Enrollment and retention of subjects in clinical trials is expensive and time-consuming and may result in additional costs and delays in our product development activities, or in the failure of such activities;
- Serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates;
- As a company, we have never obtained marketing approval for any product candidate and we may be unable to successfully do so in a timely manner, if at all, for any of our product candidates;
- Even if our lead product candidate or our other product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success;
- If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered;
- We currently have limited sales, marketing or distribution capabilities and have no experience as a company in commercializing products;

- We will need to increase the size of our organization, and we may experience difficulties in executing our growth strategy and managing any growth;
- If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop our current and any future product candidates, commercialize our product candidates or otherwise implement our business plan;
- We currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. The loss of these manufacturers, or their failure to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business;
- We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize roflumilast cream, roflumilast foam, ARQ-252, ARQ-255 or any future product candidates;
- Risks related to our intellectual property could materially adversely impact our business, competitive position, financial condition, and results of operations;
- Risks related to government regulation of our industry and required approvals could materially adversely impact our business, competitive position, financial condition, and results of operations; and
- Future litigation could have a material adverse effect on our business and results of operations;

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 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, topical roflumilast cream, has successfully completed pivotal Phase 3 clinical trials in plaque psoriasis, demonstrating symptomatic improvement and favorable tolerability in this population. We are currently preparing a New Drug Application (NDA), with a submission to the U.S. Food and Drug Administration (FDA) expected in the second half of 2021. Roflumilast 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 dermatological conditions. We are developing roflumilast cream for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. We have also successfully completed a long-term safety study of roflumilast cream in plaque psoriasis patients, showing continued symptomatic improvement and favorable tolerability over a treatment period of 52 to 64 weeks. In atopic dermatitis, we have completed a Phase 2 proof of concept study of roflumilast cream and recently initiated Phase 3 clinical trials with topline data expected in the second half of 2022.

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

Beyond this, we are developing ARQ-252, a potent and highly selective topical Janus kinase type 1, or JAK1, inhibitor. We have completed enrollment in a Phase 2b clinical study for the treatment of chronic hand eczema and expect topline data in mid-2021. We expect to initiate a Phase 2 proof of concept study of ARQ-252 for the treatment of vitiligo in the first quarter of 2021. Additionally, we have formulation and preclinical efforts underway 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.

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 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. In seborrheic dermatitis, in addition to TCS, topical antifungals are commonly used, but have limited efficacy.

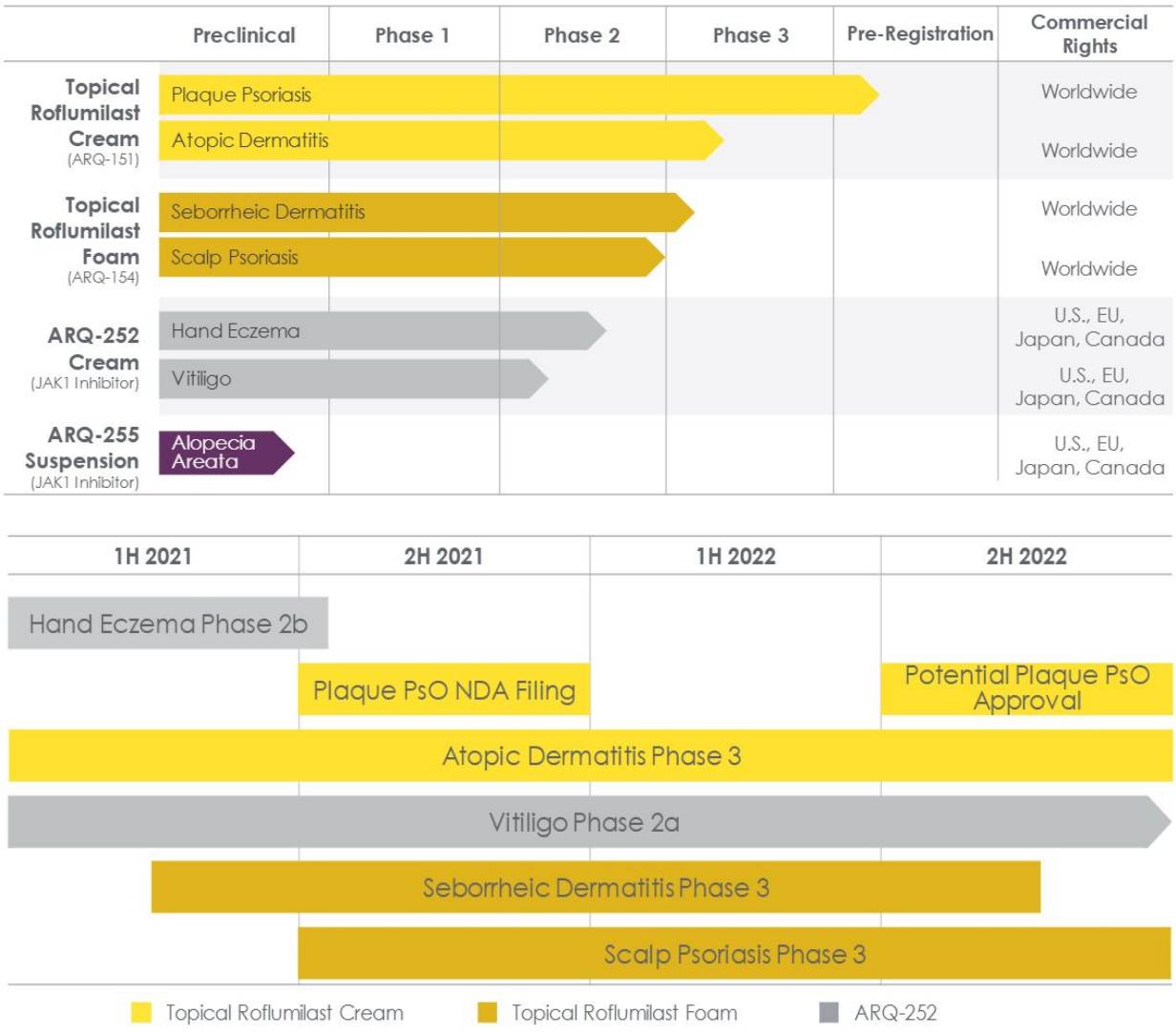
Biologic and systemic therapies are also available for some diseases, but are indicated for a small percentage of the affected population. Biologics for psoriasis and atopic dermatitis have shown impressive response rates but are only indicated for the minority of patients with moderate-to-severe forms of disease, are expensive, and often face reimbursement and access restrictions. Use of oral systemic therapies such as methotrexate and apremilast (Otezla) are also limited to more severe psoriasis patients and have significant side effect risks.

Additionally, many patients on biologic and systemic therapies still require adjunctive topical therapy 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:



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, topical 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 similar to high potency steroids while potentially delivering a low risk of side effects and a favorable tolerability profile that enables chronic administration, including for pediatric patients. In plaque psoriasis, we have successfully completed pivotal Phase 3 clinical trials, as well as a long-term safety study. We are currently preparing an NDA, with a submission to the FDA expected in the second half of 2021. In atopic dermatitis, we have completed a Phase 2 proof of concept study and recently initiated Phase 3 clinical trials with topline data expected in the second half of 2022.
- ***Expand our addressable market with topical roflumilast foam.*** We are developing a foam formulation of roflumilast for the treatment of scalp 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 had a successful End of Phase 2 meeting with the FDA and plan to initiate a single pivotal Phase 3 clinical trial in the second or third quarter of 2021, with topline data expected in the second or third quarter of 2022. Pending discussions with regulators, we expect to initiate our Phase 3 program in scalp psoriasis in the second half of 2021, with topline data anticipated in the second half of 2022.
- ***Further expand our product portfolio through the development of ARQ-252/ARQ-255.*** We are developing ARQ-252, 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 has the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition, giving it the potential to be best-in-class. We have completed enrollment in a Phase 2b clinical study for the treatment of chronic hand eczema and expect topline data in mid-2021. We expect to initiate a Phase 2 proof of concept study of ARQ-252 for the treatment of vitiligo in the first quarter of 2021. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.
- ***Establish an integrated development and commercial organization*****.** We believe the concentrated prescriber base of the U.S. dermatology segment provides us with the opportunity to build a fully integrated commercial organization and targeted sales force for the commercialization of our product candidates among dermatology specialists. To further enhance the value of our product candidates, we 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.
- ***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)
- 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 deep in the dermis where other topicals can’t reach (patent pending)

Our Market Opportunity

We believe there are significant market opportunities to capture in each of our addressable markets. The table below details the U.S. patient populations for diseases with treatments under development with topical roflumilast cream.

US Patient Populations (Millions)

	Psoriasis	Atopic Dermatitis	Seborrheic Dermatitis
Prevalence	8.6	19.2	10.0
Rx treated	3.5	6.3	2.7
Topically treated	2.5	5.4	2.7
Rx treatment in Derm Setting	2.8	1.2	1.8
Rx treated (Topically) in Derm Setting	2.0	1.0	1.8

There are additional large opportunities in diseases that we could potentially treat with ARQ-252 and ARQ-255. The U.S. prevalence for chronic hand eczema, vitiligo, and alopecia areata are approximately 8.3 million, 1.3 million, and 6.2 million patients, respectively.

Topical Roflumilast Cream (ARQ-151)

Our lead product candidate, topical roflumilast cream, has the potential to offer symptomatic improvement 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 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, crisaborole (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, and are currently preparing an NDA, with a submission to the FDA expected in the second half of 2021. In atopic dermatitis, we have completed a Phase 2 proof of concept study and recently initiated Phase 3 clinical trials. 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 approximately 400 subjects (INTEGUMENT-OLE). We anticipate topline data from INTEGUMENT-1 and -2 in the second half of 2022.

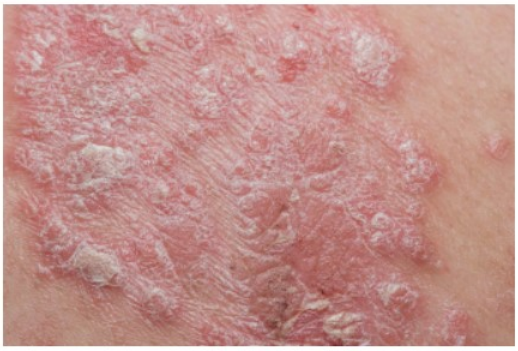
In July 2018, we executed a licensing agreement with AstraZeneca AB (AstraZeneca) for exclusive worldwide rights to roflumilast as a topical product in humans solely for dermatological indications. We have built our own intellectual property portfolio around topical uses of roflumilast, with issued and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

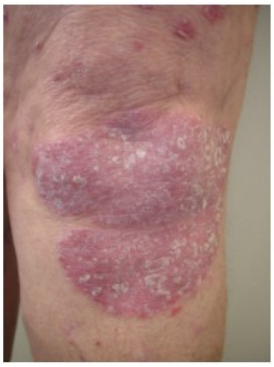
Plaque Psoriasis

Psoriasis Background

Psoriasis is an immune disease that occurs in about two percent of adults in western countries, representing approximately 8.6 million patients in the United States. About 90% of cases are plaque psoriasis, which is characterized by “plaques”, or raised, red areas of skin covered with a silver or white layer of dead skin cells referred to as “scale” (see figures below). Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and the plaques are often itchy and sometimes painful. At least 40% of plaque psoriasis patients have plaques on their scalp, 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.





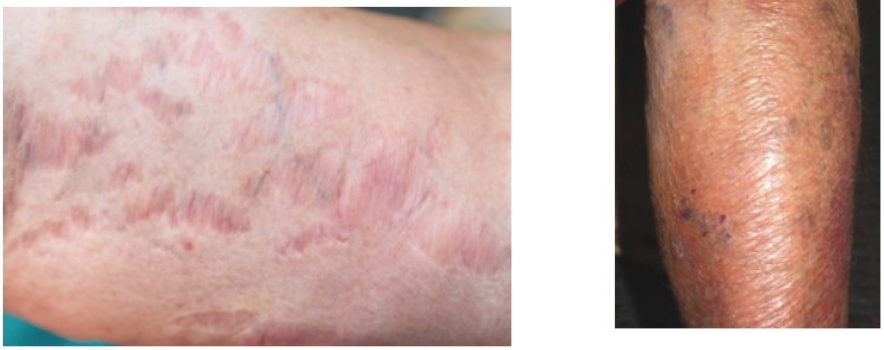
Figures: Plaque Psoriasis

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 patients 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.

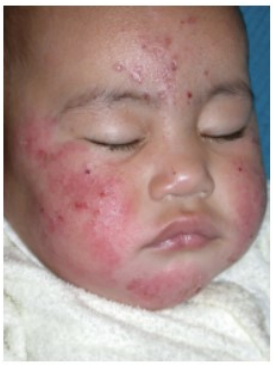
Treatment with biologics remains highly restricted. In the United States, less than 20% of moderate-to-severe psoriasis patients, equivalent to 6% of all psoriasis patients, are on biologic therapy. The uptake of biologics has remained limited due to multiple factors, including the fact that they are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

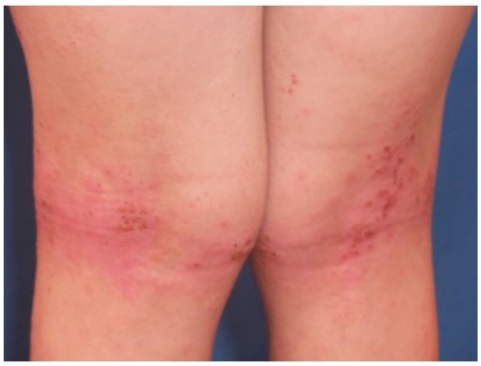
Treatment with non-biologic systemic therapy, such as methotrexate or Otezla is also limited. According to Decision Resources Group, non-biologic systemic therapy represents approximately 8% of patients worldwide and 11% of patients in the United States. The use of methotrexate has declined due to concerns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

Atopic Dermatitis

Atopic Dermatitis Background

Atopic dermatitis is the most common type of eczema, occurring in approximately 6% of the population, representing approximately 19.2 million patients in the United States. Disease onset is most common by 5 years of age, and we estimate that approximately 60% of patients suffering from atopic dermatitis are pediatric patients. Atopic dermatitis is the most common skin disease among children, affecting approximately 15% to 20% of children. 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 that most of the patients are pediatric, 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 2020. 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.

Topical Roflumilast Cream Clinical Development

Plaque Psoriasis

We have successfully completed the pivotal clinical studies of topical roflumilast cream in plaque psoriasis, and are currently preparing the NDA for submission with the FDA. We intend to use the results from the pivotal Phase 3 clinical studies, DERMIS-1 and DERMIS-2, supported by the chronic treatment results from the ARQ-151-202 and DERMIS-OLE studies, to support recommendations for long-term use. Safety data from DERMIS-1, DERMIS-2 and Study ARQ-151-202, supplemented with data from Studies ARQ-151-201, ARQ-154-204, DERMIS-OLE, and other studies, will form the basis for our Integrated Safety Summary that will be required by the FDA at the time of submission.

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 patients 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 patients treated with roflumilast cream achieved IGA Success, compared to 6.1% of patients treated with vehicle ($p < 0.0001$) in DERMIS-1, and 37.5% of patients treated with roflumilast cream achieved IGA Success, compared to 6.9% of patients 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 patients treated with roflumilast cream, five patients (1.7% of subjects) in DERMIS-1 and one patient (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 patients experiencing a treatment-related adverse event during 52 weeks of treatment. At week 52 of the long-term safety study, 44.8% of all subjects attained an Investigator Global Assessment (IGA) 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.

ARQ-151-201 (Phase 2b Study)

ARQ-151-201 was a multi-center, multi-national, double-blind, vehicle-controlled Phase 2b study, in which 331 adults with plaque psoriasis covering between 2% and 20% BSA were randomized to receive 12 weeks of: (1) roflumilast cream 0.3%, (2) roflumilast cream 0.15%, or (3) matching vehicle. At the end of the 12-week treatment period, patients were eligible to roll over into our ARQ-151-202 open label extension study for an additional 52 weeks. Completion rates for the study were 93.6% in the roflumilast cream 0.3% arm, 92.0% in the roflumilast cream 0.15% arm, and 78.9% in the vehicle arm.

On the study's primary endpoint, roflumilast cream produced statistically significant reductions compared to vehicle (roflumilast cream 0.3%: $p<0.001$, roflumilast cream 0.15%: $p = 0.004$) in the signs of plaque psoriasis, as measured by an IGA score of "clear" or "almost clear", after 6 weeks of once daily treatment, and was very well-tolerated with minimal adverse events in the study population. On one of the study's secondary endpoints, roflumilast cream 0.3% had an IGA Success (clear/almost clear + 2-grade improvement from baseline) rate of 32.2%, and roflumilast cream 0.15% had an IGA Success rate of 24.5% compared to a vehicle IGA Success rate of 9.8% (roflumilast cream 0.3%: $p<0.001$, roflumilast cream 0.15%: $p = 0.005$) after 8 weeks of once daily application. Roflumilast cream 0.3% also separated statistically from vehicle on all secondary endpoints, including reductions in Intertriginous IGA (I-IGA), Psoriasis Area Severity Index, reductions in itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS), and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary, and roflumilast cream 0.15% separated statistically from vehicle on all secondary endpoints except for I-IGA.

In this study, roflumilast cream was very well-tolerated in this population. The incidence of TEAEs was low and similar between active treatment and vehicle, with nearly all TEAEs mild to moderate in severity. Among subjects receiving roflumilast cream, there was only one discontinuation due to a TEAE (< 1% of subjects) and two Serious Adverse Events (neither related to drug).

Key Ongoing Trials

ARQ-151-306 (DERMIS-OLE) Study

A portion of subjects who completed 8 weeks of double-blind treatment in the DERMIS-1 and DERMIS-2 studies were eligible to roll over to the ongoing open label extension study, DERMIS-OLE. In this study, up to 250 subjects will be enrolled and all subjects receive roflumilast cream 0.3% for 24 weeks. The primary endpoints of this study are the occurrence of TEAEs and the occurrence of Serious Adverse Events (SAEs).

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 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 patients, 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 patients treated with roflumilast cream 0.15% compared to 4.8 in patients 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 patients 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 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 and Upcoming Trials

The atopic dermatitis Phase 3 program includes four studies. INTEGUMENT-1 and -2, which have been initiated, 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 will be 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. We anticipate topline data from INTEGUMENT-1 and -2 in the second half of 2022. 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 will be randomized to receive once daily topical application for 4 weeks of roflumilast cream 0.05%, or vehicle and the primary endpoint will also be IGA Success at week 4. INTEGUMENT-OLE is an open label extension study that will enroll approximately 400 subjects who have completed INTEGUMENT-1, -2, or -PED. Subjects will be treated for up to 52 weeks and the primary endpoint are the occurrence of TEAEs and SAEs.

Topical Roflumilast Foam

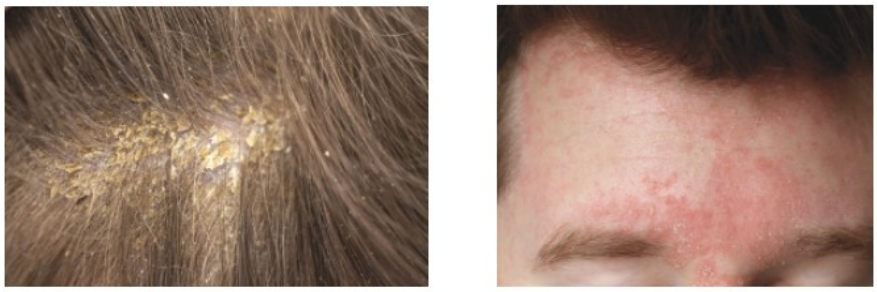
We are also developing a topical foam formulation of roflumilast for the treatment of scalp psoriasis and seborrheic dermatitis. Topical roflumilast foam contains the same highly potent and selective PDE4 inhibitor found in topical roflumilast cream, and is nearly identical to topical roflumilast cream, 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 psoriasis, demonstrating promising efficacy and tolerability in both diseases. 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 approximately 2% of the population. The disease causes red patches covered with large, greasy, flaking yellow-gray scales, and is frequently itchy. It appears most often on the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back as depicted in the figure below. A milder variant of the disease is dandruff. While the pathogenesis of seborrheic dermatitis is not well understood, some experts believe a contributor is an over-abundance of *Malassezia*, a naturally occurring yeast found on normal skin but found in excess numbers on skin with seborrheic dermatitis. There also is an immunological or inflammatory component, possibly as a result of the proliferation of the *Malassezia* yeast and its elaboration of substances that irritate the skin. Seborrheic dermatitis can occur in both adults and infants, and in infants is commonly referred to as “cradle cap”.



Figures: Seborrheic Dermatitis

Current Seborrheic Dermatitis Treatment Landscape

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

- **Antifungal agents**, particularly azoles such as ketoconazole, are the cornerstone of therapy for seborrheic dermatitis. These agents are available in a variety of 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).

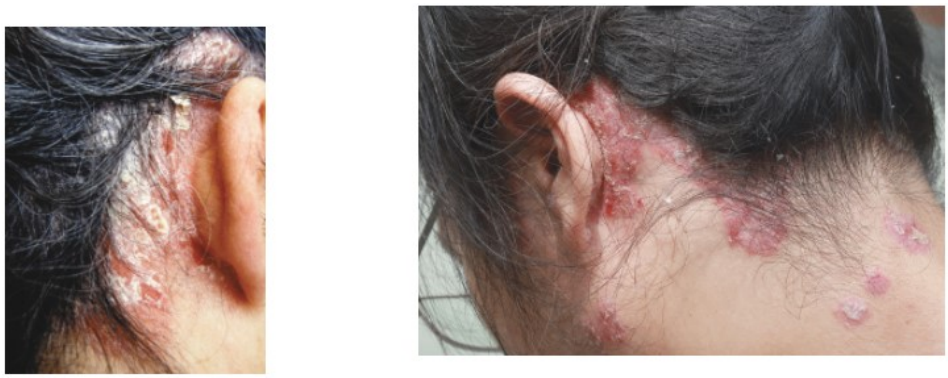
While physicians have a number of relatively inexpensive treatment options that provide symptomatic improvement for seborrheic dermatitis, the greatest unmet need relates to inadequate response to existing therapies in some patients, particularly in patients with more severe disease. Physicians report 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 topical 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 preclinical 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 figure below. These psoriatic plaques are identical to plaques on other body areas, however topical treatment of these plaques is complicated by the difficulty of delivering topical drugs under hair-bearing areas. As with psoriatic plaques on other parts of the body, psoriasis on the scalp is often itchy and is sometimes painful. Scalp psoriasis can also be associated with hair loss, likely due to damage to the hair from excessive scratching, rubbing, or combing of the affected area.



Figures: Scalp Psoriasis
Source: 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.

Topical Roflumilast Foam Clinical Development

We have successfully completed Phase 2 studies of roflumilast foam in seborrheic dermatitis and scalp psoriasis. In seborrheic dermatitis, we had a successful End of Phase 2 meeting with the FDA and plan to initiate a single pivotal Phase 3 clinical trial in the second or third quarter of 2021, with topline data expected in the second or third quarter of 2022. Pending discussions with regulators, we expect to initiate our Phase 3 program in scalp psoriasis in the second half of 2021, with topline data anticipated in the second half of 2022.

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-154-214 (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 patients with seborrheic dermatitis. This study includes patients who were treated previously in the Phase 2 trial (ARQ-154-203), as well as patients naive to treatment with roflumilast foam. Periodic clinic visits will include assessments for clinical safety, application site reactions, and disease improvement, or progression.

ARQ-154-304 (Phase 3 Study)

The Phase 3 program will consist of a single pivotal trial, which we anticipate initiating in the second or third quarter of 2021, with topline data expected in the second or third quarter of 2022.

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.

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 preclinical study, ARQ-252 proved to be highly selective to JAK1 over JAK2, in contrast to ruxolitinib, the furthest advanced topical Janus kinase, or JAK, inhibitor in U.S. development. 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.

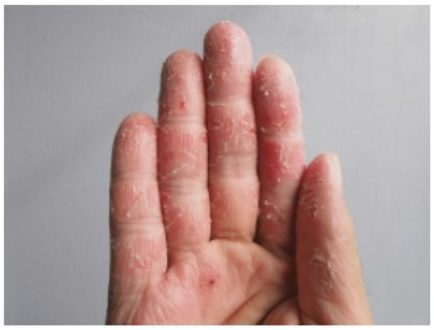
We have completed enrollment in a Phase 2b clinical study for the treatment of chronic hand eczema with ARQ-252, and expect topline data in mid-2021. We expect to initiate a Phase 2 proof of concept study of ARQ-252 for the treatment of vitiligo in the first quarter of 2021. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

In 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)

We have completed enrollment in the ARQ-252-205 Study. This study is a multi-center, multi-national, double-blind, randomized, vehicle-controlled Phase 2b study, in which approximately 215 adults with chronic hand eczema were randomized to receive: (1) 0.1% ARQ-252 cream applied once daily, or (2) 0.3% ARQ-252 cream applied once daily, or (3) 0.3% ARQ-252 cream applied twice daily, or (4) matching vehicle cream applied once or twice daily, all for 12 weeks. The primary efficacy endpoint is IGA Success, defined as an IGA of "clear" or "almost clear" plus at least a 2-point improvement from baseline at week 12. We expect to report topline data by mid-2021.

Vitiligo

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

We expect to initiate enrollment in the ARQ-252-213 study in the first quarter of 2021. This Phase 2a study is a parallel group, double blind, vehicle-controlled study of the safety and efficacy of ARQ-252 0.3% cream either with or without narrowband UVB (NB-UVB) phototherapy treatment in approximately 500 subjects with non-segmental facial vitiligo. The primary endpoint of the study is the proportion of subjects achieving Facial Vitiligo Area Scoring Index-75 (F-VASI-75), which is ≥ 75% improvement from baseline in F-VASI at week 24.

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 preclinical experiments are underway to develop a 4D version of ARQ-252, which we refer to as ARQ-255, and if those formulation efforts are successful, we plan to enter the clinic with ARQ-255 as a potential treatment for alopecia areata.

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., deucravacitinib, an oral Tyrosine kinase type 2 (Tyk2) inhibitor under development by BMS, Inc., and PF-06700841, a Tyk2/JAK1 inhibitor under development by Pfizer, Inc.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., and generic and branded versions of low to mid-potency steroids such as hydrocortisone and betamethasone; and the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with roflumilast cream, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc. (approved as Corectim in Japan), topical PF-06700841, a Tyk2/JAK1 inhibitor under development by Pfizer, Inc., topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, oral PF-04965842, under development by Pfizer Inc., oral upatacitinib, under development by AbbVie, Inc. and injectable lebrikizumab, under development by Eli Lilly and Company.

For hand eczema, our primary competitors include topical therapies such as branded and generic versions of clobetasol, such as Clobex, and generic versions of betamethasone dipropionate. The only other prescription product candidate we are aware of under development for the treatment of hand eczema that would compete with ARQ-252 is delgocitinib, 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., topical ruxolitinib, under development by Incyte Corporation, and both oral PF-06651600 and oral PF-06700841, under development by Pfizer Inc.

For alopecia areata, our primary competitors include topical therapies such as branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; intralesional corticosteroid injections such as branded and generic versions of triamcinolone, including Kenalog, marketed by Bristol-Myers Squib; and systemic immunosuppressants including generic versions of systemic steroids such as prednisone, branded and generic versions of cyclosporine, including Sandimmune, marketed by Sandoz, and branded systemic JAK inhibitors, including Xeljanz, marketed by Pfizer, Inc.. In addition, there are several prescription product candidates under development that could potentially be used to treat alopecia areata and compete with ARQ-255, including but not limited to: 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 intend to begin building this commercial infrastructure if and when we believe that a regulatory approval of our first product candidate appears reasonably likely. We plan to build our own small specialty sales force targeted at dermatologists, with approximately 100 field-based staff needed to market to US dermatologists. 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 also plan to build the required sales management, marketing, access and reimbursement, sales support, and distribution capabilities to optimize our commercial success. To develop the required commercial infrastructure, we will have to invest substantial financial and management resources, some of which will be committed prior to any confirmation that our product candidates will be approved, and we could invest resources and then later learn that a particular product candidate is not being approved. We may also seek other partners to help us access other geographic markets.

Intellectual Property

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

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

As of February 16, 2021, we own or have an exclusive license to ten issued U.S. patents and eight issued foreign patents, which include granted European patent rights that have been validated in various European Union (EU) member states, and five pending U.S. patent applications, 15 pending foreign patent applications and two applications filed under the Patent Corporation Treaty. Of these patents and patent applications:

- **Roflumilast cream & roflumilast foam**: As of February 16, 2021, we own five issued U.S. patents, one issued Canadian patent, one issued Japanese patent, one issued Chinese patent, seven pending U.S. patent applications and 39 pending foreign applications (two each in Hong Kong and Canada; three each in Japan, Mexico, New Zealand, India, Australia, Europe, Israel, and Brazil, China, Korea and Eurasia; and two 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. 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 16, 2021, we have an exclusive license from Hengrui to five issued U.S. patents, two issued Japanese patents, and three issued EU patents (validated in a number of EU member states, including Austria, Belgium, Bulgaria, Croatia, the Czech Republic, Estonia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxemburg, Monaco, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovenia, Slovakia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom), 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 anticipate filing patent applications directed towards formulations, methods and other aspects of our technology relating to ARQ-252 and ARQ-255 which we may develop in the future.

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

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

Exclusive License and Option Agreements

AstraZeneca

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 Preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product. We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $12.5 million upon the achievement of specific regulatory approval milestones with respect to the AZ-Licensed Products and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on 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. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

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

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

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

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, requirements, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

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

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

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

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

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the additional information must be included in any resubmitted NDA, which is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the Prescription Drug User Fee Act, guidelines that are currently in effect, the FDA has a goal of ten months from the date of receipt of a standard NDA for a product that is not a new molecular entity, or NME, and six months from the date of receipt for an NDA for a non-NME subject to priority review, to review and act on the submission. In the case of an NME, the six and ten month review periods are measured from the date on which the FDA "files" the NDA rather than the date on which the NDA is received by the FDA. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

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

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

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

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

Certain changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of these clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act as amended and reauthorized, certain NDAs or supplements to NDAs must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority review applications, with all of the benefits that designation confers.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA. For instance, the FDA closely regulates the post-approval labeling, marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. There also are continuing, annual program fee requirements for any marketed products.

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

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

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

Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or PDMA. In addition, the Drug Supply Chain Security Act, or DSCSA, has imposed new “track and trace” requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten year period. The DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug “pedigree” requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA’s new national licensing standard, current state licensing requirements typically remain in effect.

The Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA’s prior findings of safety and efficacy for an existing product, or published literature, in support of its application. However, a drug must meet certain criteria relative to the Listed Drug to be eligible to use the Section 505(b)(2) pathway as opposed to the abbreviated 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 preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Orange Book Listing

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

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

A certification that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the application until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant.

The application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

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

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

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

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable PTE is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office (USPTO) must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other Healthcare Laws

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

The 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 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. Effective January 1, 2022, reporting on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse-midwives will also be required.

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

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

Coverage and Reimbursement

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

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

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

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

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

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

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the 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 and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The Tax Cuts and Jobs Act of 2017, or TCJA, was enacted by the prior presidential administration and congress, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case but it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

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, 2021, 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 recent presidential election.

Human Capital Resources and Employees

As of December 31, 2020, we had 54 full-time employees. Of these full-time employees, 10 have an M.D., a Ph.D. or a Pharm. D. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

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 U.S. Securities and Exchange Commission (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 preclinical studies and conducting clinical trials for our product candidates.

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

Our net loss for the years ended December 31, 2020 and 2019 was approximately $135.7 million and $42.0 million, respectively. As of December 31, 2020, we had an accumulated deficit of $202.0 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. We may never achieve profitability and, even if we do, we may not be able to sustain profitability in subsequent periods. We will continue to incur significant research and development and other expenses related to our ongoing operations and the development of our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital.

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

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

Since our inception, we have invested substantially all of our efforts and financial resources in research and development activities, and we expect to continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates, roflumilast cream, roflumilast foam, ARQ-252 and ARQ-255, the development or acquisition of additional product candidates and the maintenance and expansion of our business operations and capabilities. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and securing manufacturing and supply of product candidates, and marketing and selling any products approved for sale. These expenditures may also include costs associated with in-licensing dermatology assets consistent with our core strategy. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we

cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our lead product candidates and any future product candidates.

As of December 31, 2020, we had capital resources consisting of cash, cash equivalents and marketable securities of $284.4 million. In addition, we completed an equity offering on February 5, 2021, receiving approximately $207.4 million in net proceeds, after deducting underwriting discounts, commissions and estimated offering expenses. Based on our planned operations, we believe that our existing cash, cash equivalents and marketable securities, along with the cash that we received in February related to our financing, will be sufficient to fund our operations into 2023. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

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

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

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

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

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

- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

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

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

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot assure you of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this 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.

Risks Related to Development and Commercialization

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

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

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate, particularly as a result of the impact of the COVID-19 pandemic, and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;

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

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, our Phase 2 proof of concept study in atopic dermatitis had a limited number of patients and did not reach statistical significance for the primary endpoint or the secondary endpoint of IGA Success. However, this study did provide evidence that roflumilast cream could provide symptomatic improvement 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. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Patient enrollment is affected by other factors including:

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

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

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

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

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

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

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

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

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

Conducting Phase 3 clinical trials and preparing, and obtaining marketing approval for, a product candidate is a complicated process. Although members of our management team have participated in pivotal trials and obtained marketing approvals for product candidates in the past while employed at other companies, we as a company have limited experience doing so. As a result, these activities may require more time and cost more than we anticipate, and we may be unable to successfully complete them for any of our product candidates.

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

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

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

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

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

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

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

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

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

As to any of our product candidates that become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently

become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our prescription-only products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

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

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

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

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

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

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

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

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

others. Failure to obtain a marketing approval in countries in which we seek to market our products or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for any of our products.

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

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

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

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

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

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

The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for our targeted inflammatory and medical dermatological indications. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies or drugs that become available in the future for the treatment of our target

indications. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Even if another branded or generic product or OTC product is less effective than our product candidates, a less effective branded, generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience.

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

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

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

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., and generic and branded versions of low to mid-potency steroids such as hydrocortisone and betamethasone; and the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with roflumilast cream, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc., topical PF-06700841, a Tyk2/JAK1 inhibitor under development by Pfizer, Inc., topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, oral PF-04965842, under development by Pfizer Inc., oral upatacitinib, under development by AbbVie, Inc., and injectable lebrikizumab, under development by Eli Lilly and Company.

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

For vitiligo, our primary competitors include topical therapies such as generic and branded versions of calcineurin inhibitors, including Elidel, marketed by Bausch Health; branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat vitiligo and compete with ARQ-252, including but not limited to: topical cerdulatinib, under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, and both oral PF-06651600 and oral PF-06700841, under development by Pfizer Inc.

For alopecia areata, our primary competitors include topical therapies such as branded and generic versions of high potency steroids, including Clobex, marketed by Galderma Laboratories, LP; intralesional corticosteroid injections such as branded and generic versions of triamcinolone, including Kenalog, marketed by Bristol-Myers Squib; and systemic immunosuppressants including generic versions of systemic steroids such as prednisone, branded and generic versions of cyclosporine, including Sandimmune, marketed by Sandoz, and branded systemic JAK inhibitors, including Xeljanz, marketed by Pfizer, Inc. In addition, there are several prescription product candidates under development that could potentially be used to treat alopecia areata and compete with ARQ-255, including but not limited to: topical PF-06700841 and oral PF-06651600, under development by Pfizer, Inc., oral CTP-543, under development by Concert Pharmaceuticals, and oral baricitinib, under development by Eli Lilly and Company.

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

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

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

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

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

Risks Related to Our Business and Operations

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

As of December 31, 2020, we had 54 full-time employees. We will need to continue to expand our managerial, clinical, commercial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our lead product candidates or any future product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

We currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. 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 nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. Instead, we currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. As of the second quarter of 2020, we have successfully manufactured and tested several batches of our product candidate at our primary commercial site and 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 scale.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a

license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The current presidential administration and U.S. Congress have sought and will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. For example, the TCJA was enacted, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case but it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA, our business or financial condition.

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an

"emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

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

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

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

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

As of December 31, 2020, our executive officers, directors and their respective affiliates beneficially owned approximately 45% of our voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position, including the ability to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of approximately 25.8 million shares of our common stock (including 1.4 million shares issued and sold pursuant to the private placement of shares in connection with our follow-on financing) have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

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

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

As of December 31, 2020, 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 $180.7 million, $180.8 and $3.2 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 $177.2 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 $6.4 million and $1.4 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. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

General Risk Factors

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. For example, outbreaks of epidemic, pandemic, or contagious diseases, such as the recent COVID-19 outbreak, could disrupt our business. Business disruptions could include disruptions to the enrollment, clinical site availability, patient accessibility and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, the COVID-19 outbreak may result in a severe economic downturn and has already significantly affected the financial markets of many countries. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 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 11, 2021, there were approximately 24 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.

Dividend Policy

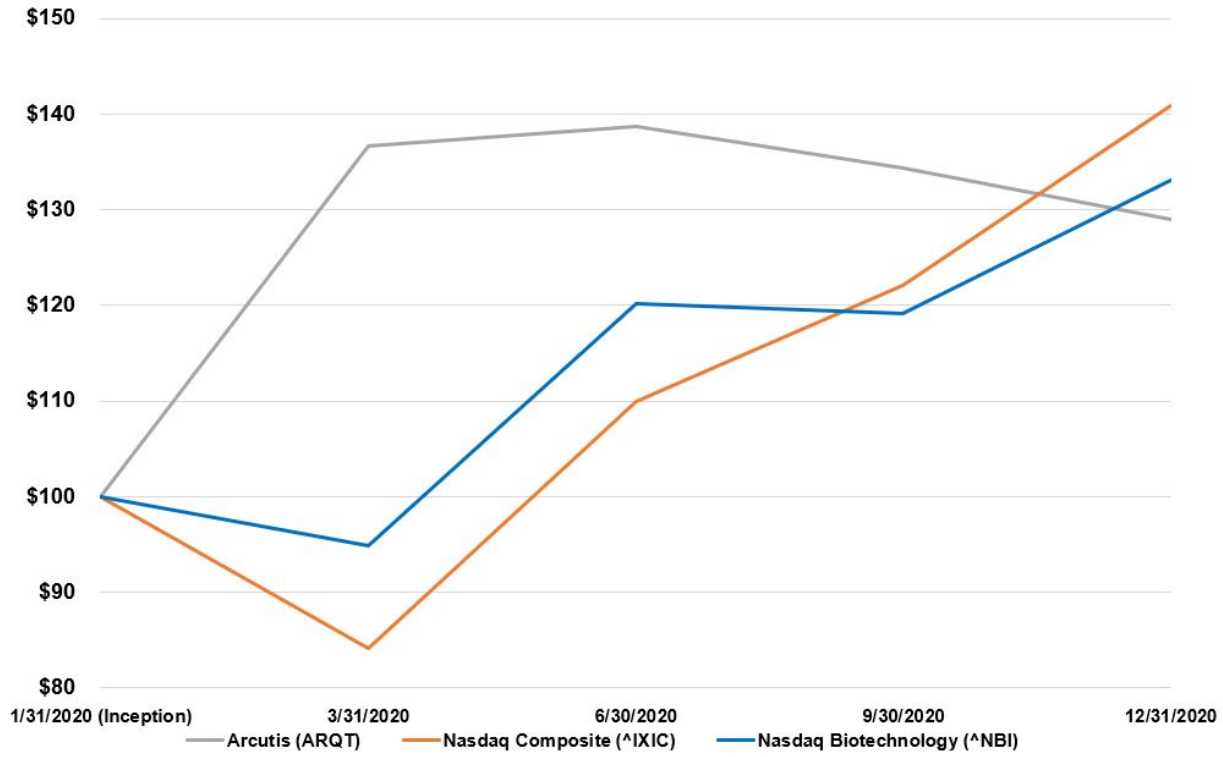
We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination 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 5 regarding equity compensation plans is incorporated by reference from the information under the captions “Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” that will be contained in 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, 2020, 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)	3/31/2020	6/30/2020	9/30/2020	12/31/2020
Arcutis Biotherapeutics, Inc.	$100.00	$136.70	$138.72	$134.40	$129.04
Nasdaq Composite Index	$100.00	$84.15	$109.92	$122.04	$140.84
Nasdaq Biotechnology Index	$100.00	$94.90	$120.23	$119.09	$133.14

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On January 30, 2020, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-235806 and File No. 333-236177), as amended, filed in connection with our IPO. There has been no material change in the planned use of proceeds from our IPO from that described in the related prospectus dated January 30, 2020, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2020.

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, 2020, 2019 and 2018, and the selected balance sheet data as of December 31, 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,		
	2020	2019	2018
	(in thousands, except share and per share data)		
Statements of operations data:			
Operating expenses:			
Research and development	$ 115,308	$ 36,522	$ 17,940
General and administrative	21,337	6,610	1,795
Total operating expenses	136,645	43,132	19,735
Loss from operations	(136,645)	(43,132)	(19,735)
Other income, net	967	1,136	480
Net loss	$ (135,678)	$ (41,996)	$ (19,255)
Net loss per share, basic and diluted[(1)]	$ (3.80)	$ (22.78)	$ (15.53)
Weighted-average shares used in computing net loss per share, basic and diluted[(1)]	35,668,152	1,843,213	1,239,689

(1) See Notes 2 and 11 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,	
	2020	2019
	(in thousands)	
Balance sheet data:		
Cash, cash equivalents, restricted cash and marketable securities	$ 285,983	$ 101,265
Working capital[(1)]	270,224	101,237
Total assets	298,269	107,012
Convertible preferred stock	—	166,491
Accumulated deficit	(201,950)	(66,272)
Total stockholders' equity (deficit)	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 platform and deep dermatology expertise to develop differentiated products that have the potential to address the major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

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

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

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

Beyond this, we have completed enrollment in a Phase 2b clinical study of ARQ-252, a potent and highly selective topical JAK1 inhibitor for the treatment of chronic hand eczema, and expect topline data by mid-2021. We also plan to initiate a Phase 2 proof of concept study of ARQ-252 for the treatment of vitiligo in the first quarter of 2021. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

Since our inception in 2016, we have invested a significant portion of our efforts and financial resources in clinical development activities. We have not generated any revenue from product sales and have funded our operations primarily with the net proceeds from our IPO completed in January and with the net proceeds from our follow-on equity offerings in October 2020 and February 2021 respectively, as well as with $162.5 million in net cash proceeds from private placements of our convertible preferred stock prior to IPO. On February 4, 2020, we closed our IPO of 10,781,250 shares of common stock at an offering price of $17.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 1,406,250 additional shares of common stock. Our net proceeds, after deducting underwriting discounts, commissions and offering related transaction costs, were $167.2 million. In addition, on October 6, 2020, we closed our public offering of 4,000,000 shares of common stock and concurrent private placement of 1,400,000 shares of common stock, both at a price of $25.00 per share, receiving an aggregate of $128.4 million in net proceeds after deducting the underwriting discounts, commissions and offering related transaction costs. Also, on February 5, 2021, we closed our public offering of 6,325,000 shares of common stock at a price of $35.00 per share, including 825,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, receiving approximately $207.4 million in aggregate net proceeds, after deducting underwriting discounts, commissions and estimated offering expenses. See Note 13 to the financial statements for additional information.

We have incurred net losses in each year since inception, including net losses of $135.7 million, $42.0 million and $19.3 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $202.0 million and cash, cash equivalents, restricted cash and marketable securities of $286.0 million.

We expect to continue to incur losses for the foreseeable future and expect to incur increased expenses as we advance our product candidates through clinical trials and regulatory submissions. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval or clearance from the FDA or other foreign regulatory authorities for our product candidates. If we obtain regulatory approval or clearance for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue preclinical studies and clinical trials for, and research and development of, our product candidates and maintain, expand and protect our intellectual property portfolio. As a result, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through equity or debt financings or other sources, such as future potential collaboration agreements. Our failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations and financial condition. See “—Liquidity, Capital Resources and Requirements” below and Note 1 to the financial statements for additional information. Based on our current planned operations, we expect that our current cash, cash equivalents and marketable securities, along with the cash proceeds received in February 2021 related to our financing, will be sufficient to fund our operations into 2023.

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

COVID-19 Update

In March 2020, the World Health Organization declared a pandemic related to the COVID-19 outbreak. COVID-19 has placed strains on the providers of healthcare services, including the sites where we conduct our clinical trials. These strains have resulted in some clinical sites slowing or halting enrollment in clinical trials and restricting the on-site monitoring of clinical trials. We follow FDA guidance on clinical trial conduct during the COVID-19 pandemic, including the remote monitoring of clinical data. We are monitoring the impact COVID-19 may have on the clinical development of our product candidates, including potential delays or modifications to ongoing and planned trials. Thus far, we have seen limited impact on our clinical trials including some disruptions in screening, enrollment and monitoring, however at this time, we do not expect delays to previously disclosed clinical timelines, including those for roflumilast cream, roflumilast foam and ARQ-252. We cannot, at this time, predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on our ongoing and planned clinical trials and other business operations.

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

In alignment with public health guidance designed to slow the spread of COVID-19, we implemented a remote work plan for all employees as of mid-March 2020. We 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 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 EU (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 preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. Research and development costs are expensed as incurred. These costs include direct program expenses, which are payments made to third parties that specifically relate to our research and development, such as payments to clinical research organizations, clinical investigators, manufacturing of clinical material, preclinical testing and consultants. In addition, employee costs, including salaries, payroll taxes, benefits, stock-based compensation and travel, for employees contributing to research and development activities are classified as research and development costs. We allocate direct external costs to our product candidates; internal costs are not allocated to specific product candidates.

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

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

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

General and Administrative Expenses

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

Results of Operations

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	$	%
	(unaudited) (in thousands)			
Direct Costs:				
Preclinical and clinical	$ 82,529	$ 23,097	59,432	257 %
Manufacturing	13,383	3,481	9,902	284 %
Product milestones	—	3,500	(3,500)	(100)%
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 clinical trial costs of $59.4 million, an increase in manufacturing costs of $9.9 million, an increase in compensation and personnel-related expenses of $9.2 million, and an increase of $3.8 million in other costs, including regulatory, research and clinical consulting costs, partially offset by a decrease in licensing milestones of $3.5 million. The increases in clinical trial and manufacturing costs relate primarily 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, and the ARQ-252 Phase 2 study for hand eczema. The increase in compensation and personnel-related expenses, which includes stock compensation, was primarily due to an increase in headcount. Licensing milestones consisted of a $2.0 million cash milestone payment made to AstraZeneca in August 2019 and a $1.5 million cash option payment to Hengrui in December 2019.

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.

Comparison of the Year Ended December 31, 2019 and 2018

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

	Year Ended December 31,		Change	
	2019	2018	$	%
	(in thousands)			
Operating expenses:				
Research and development	$ 36,522	$ 17,940	$ 18,582	104 %
General and administrative	6,610	1,795	4,815	268 %
Total operating expenses	$ 43,132	$ 19,735	$ 23,397	119 %
Loss from operations	(43,132)	(19,735)	(23,397)	119 %
Other income, net	1,136	480	656	137 %
Net loss	$ (41,996)	$ (19,255)	$ (22,741)	118 %

Research and Development Expenses

	Year Ended December 31,		Change	
	2019	2018	$	%
	(unaudited) (in thousands)			
Direct Costs:				
Preclinical and clinical	$ 23,097	$ 8,448	$ 14,649	173 %
Manufacturing	3,481	2,493	988	40 %
Product milestones	3,500	4,400	(900)	(20)%
Indirect Costs:				
Compensation and personnel-related	4,590	1,566	3,024	193 %
Other	1,854	1,033	821	79 %
Total research and development expense	$ 36,522	$ 17,940	$ 18,582	104 %

Research and development expenses increased by $18.6 million, or 104%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. The increase was due to an increase in clinical trial costs of $14.6 million, an increase in compensation and personnel-related expenses of $3.0 million, and an increase in manufacturing costs of $1.0 million. The increases in clinical trial and manufacturing costs relate to the initiation of the Phase 2b and open label extension studies in roflumilast cream for plaque psoriasis in the second half of 2018 and the initiation of the Phase 2 study in roflumilast cream in atopic dermatitis in early 2019. 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 $4.8 million, or 268%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. The increase was primarily due to an increase in professional services associate with the general growth of the business of $2.3 million, which includes legal, tax, audit, market research studies and various other administrative functions, as well as an increase of $2.1 million in compensation and personnel-related expenses, which includes stock compensation, due to an increase in headcount.

Other Income, Net

Other income, net increased by $0.7 million, or 137%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. The increase was primarily due to interest earned on marketable securities, in which we had larger balances in 2019 than in 2018 due to the timing of issuances of our Series B and C convertible preferred stock.

Liquidity, Capital Resources and Requirements

Sources of Liquidity

We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. As of December 31, 2020 and 2019, we had cash, cash equivalents, restricted cash and marketable securities of $286.0 million and $101.3 million, respectively, and an accumulated deficit of $202.0 million and $66.3 million, respectively. In addition, on February 5, 2021, we completed an equity offering and received approximately $207.4 million in aggregate net proceeds, after deducting underwriting discounts, commissions and estimated offering expenses. We anticipate that operating losses and net cash used in operating activities will increase over the next several years as we further develop roflumilast cream, roflumilast foam, ARQ-252 and ARQ-255, move into later and more costly stages of product development, develop new product candidates, hire personnel and prepare for regulatory submissions and the commercialization of our product candidates.

We have historically financed our operations primarily through private placements of preferred stock, as well as our IPO completed in January 2020 and our follow-on equity offerings in October 2020 and February 2021, and 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.

Cash Flows

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

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Cash used in operating activities	$ (113,033)	$ (42,836)	$ (14,085)
Cash used in investing activities	(181,824)	(26,325)	(11,532)
Cash provided by financing activities	298,145	93,103	61,593
Net increase in cash, cash equivalents and restricted cash	$ 3,288	$ 23,942	$ 35,976

Net Cash Used in Operating Activities

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.

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

Net Cash Used in Investing Activities

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.

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

Net Cash Provided by Financing Activities

During the 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.

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

Funding Requirements

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $202.0 million and $66.3 million as of December 31, 2020 and 2019, respectively. We had cash, cash equivalents and marketable securities of $284.4 million and $101.3 million as of December 31, 2020 and 2019, respectively. In addition, on February 5, 2021, we received approximately $207.4 million in net proceeds from an equity offering, after deducting underwriting discounts, commissions and estimated offering expenses. Based on our current planned operations, we expect that our current cash, cash equivalents and marketable securities, along with the cash proceeds from our financing in February 2021, will be sufficient to fund our operations into 2023. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

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

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

- the scope, progress, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our planned or ongoing clinical studies of roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast foam in seborrheic dermatitis and scalp psoriasis, ARQ-252 in hand eczema and vitiligo, and our formulation and preclinical efforts for ARQ-255 in alopecia areata.
- suspensions or delays in the enrollment or changes to the number of patients we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead product candidate or our other product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our lead product candidates or any future product candidates and any products we successfully commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities if our lead product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of building a sales force in anticipation of product commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the costs related to milestone payments to AstraZeneca or Hengrui, upon the achievement of predetermined milestones;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, and the outcome of this and any other future patent litigation we may be involved in; and
- the timing, receipt and amount of sales of any future approved products, if any.

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of December 31, 2020:

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

In April 2020, we amended our lease agreement for our facility in Westlake Village, California to relocate to a new expanded space including 22,643 square feet. The lease payment term for the new space began on December 30, 2020 and will terminate 91 months thereafter, with a renewal option 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 provides for a leasehold improvement allowance up to $1.25 million. It also required that we deliver a letter of credit to the landlord of $1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, in November 2020, we entered into a letter of credit for $1.5 million, which is secured with a restricted cash account in the same amount.

Indemnification

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

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Use of Estimates

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.

Preclinical and Clinical Accruals and Costs

We record accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical studies, clinical trials and contract manufacturing activities. These costs are a significant component of our research and development expenses. Research and development costs are expensed as incurred unless there is an alternative future use in other research and development projects. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with third-party service providers under the service agreements. As it relates to clinical trials, the financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized. 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, 2020 and 2019 and actual costs incurred.

Stock-Based Compensation

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

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

Fair value of common stock—see the subsection titled "Common Stock 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 have sufficient trading history for our common stock, the expected volatility was estimated based on the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our stock price becomes available.

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

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

See Note 9 to our audited financial statements 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 $7.9 million, $0.8 million, and $0.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, there was $23.2 million of unrecognized compensation expense related to unvested options, which are expected to be recognized over a weighted-average period of approximately 3.4 years. As of December 31, 2020, there was $3.6 million of unrecognized compensation expense related to restricted stock, which are expected to be recognized over a weighted-average period of approximately 3.6 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, 2020, we had net deferred tax assets of $45.6 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, 2020, we had federal, California and other state NOL carryforwards of $180.7 million, $180.8 million and $3.2 million, respectively, available to potentially offset future taxable income. As of December 31, 2020, we also had federal and California research and development tax credit carryforwards of approximately $6.4 million and $1.4 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.

Emerging Growth Company Status

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

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

Item 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, 2020, we had cash and cash equivalents of $65.1 million, restricted cash of $1.5 million and marketable securities of $219.4 million, which consist of bank deposits, money market funds, commercial paper and government securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of December 31, 2020.

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

Inherent Limitations on Effectiveness of Controls and Procedures

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

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 our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2020, the end of the period covered by this Annual Report on Form 10-K. Management based its 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 our assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting during the most recent fiscal quarter 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.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Item 9B. OTHER INFORMATION

None.

Part III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the applicable information set forth in "Executive Officers," "Election of Directors," "Corporate Governance," and Section 16(a) Beneficial Ownership Reporting Compliance" which will be included in our Proxy Statement for our 2021 Annual Meeting of Stockholders, or the Proxy Statement, to be filed with the SEC.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the applicable information set forth in "Executive Compensation," and "Director Compensation" and "Corporate Governance" which will be included in our definitive Proxy Statement.

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

The information required by this item is incorporated by reference from the applicable information set forth in "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" which will be included in our definitive Proxy Statement.

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

The information required by this item is incorporated by reference from the applicable information set forth in "Certain Relationships and Related Party Transactions" and "Corporate Governance" which will be included in our definitive Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the applicable information set forth in “Ratification of Selection of Independent Registered Public Accounting Firm” which will be included in our definitive Proxy Statement.

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

10.21#	Severance & Change in Control Agreement, by and between the Registrant and Kenneth A. Lock.	S-1/A	1/21/20	10.21	
10.22#	Severance & Change in Control Agreement, by and between the Registrant and Patricia A. Turney.	S-1/A	1/21/20	10.22	
10.23#	Offer Letter, dated December 18, 2020, by and between the Registrant and Matthew R. Moore.				X
10.24#	Severance & Change in Control Agreement, by and between the Registrant and Matthew R. Moore.				X
10.25†^	Supply Agreement, dated November 24, 2020, by and between Registrant and Interquim, S.A.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included in the signature page to this Annual Report on Form 10-K).				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.
^ Registrant has omitted schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.
# 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, 2020 and 2019, the related statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits include performing procedures to assess the risks of material misstatement on the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

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

Los Angeles, California

February 16, 2021

ARCUTIS BIOTHERAPEUTICS, INC.

Balance Sheets

(In thousands, except share and par value)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,082	$ 63,336
Restricted cash	1,542	—
Marketable securities	219,359	37,929
Prepaid expenses and other current assets	6,843	5,209
Total current assets	292,826	106,474
Property and equipment, net	2,016	227
Operating lease right-of-use asset	3,349	264
Other assets	78	47
Total assets	$ 298,269	$ 107,012
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 7,140	$ 1,405
Accrued liabilities	15,462	3,654
Operating lease liability	—	178
Total current liabilities	22,602	5,237
Operating lease liability, noncurrent	4,964	129
Other long-term liabilities	82	184
Total liabilities	27,648	5,550
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.0001 par value; no shares and 48,787,898 shares authorized at December 31, 2020 and December 31, 2019, respectively; no shares and 24,385,388 shares issued and outstanding at December 31, 2020, and December 31, 2019, respectively; aggregate liquidation preference of $166,300 at December 31, 2019	—	166,491
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and no shares authorized at December 31, 2020 and December 31, 2019, respectively; no shares issued and outstanding at December 31, 2020 and December 31, 2019;	—	—
Common stock, $0.0001 par value; 300,000,000 and 65,820,000 shares authorized at December 31, 2020 and December 31, 2019, respectively; 43,677,817 and 2,879,763 shares issued at December 31, 2020 and December 31, 2019, respectively; 43,338,438 and 2,120,853 shares outstanding at December 31, 2020 and December 31, 2019, respectively	4	—
Additional paid-in capital	472,569	1,244
Accumulated other comprehensive loss	(2)	(1)
Accumulated deficit	(201,950)	(66,272)
Total stockholders' equity (deficit)	270,621	(65,029)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 298,269	$ 107,012

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,		
	2020	2019	2018
Operating expenses:			
Research and development	$ 115,308	$ 36,522	$ 17,940
General and administrative	21,337	6,610	1,795
Total operating expenses	136,645	43,132	19,735
Loss from operations	(136,645)	(43,132)	(19,735)
Other income, net	967	1,136	480
Net loss	$ (135,678)	$ (41,996)	$ (19,255)
Other comprehensive loss:			
Unrealized loss on marketable securities	(1)	(1)	—
Comprehensive loss	$ (135,679)	$ (41,997)	$ (19,255)
Per share information:			
Net loss per share, basic and diluted	$ (3.80)	$ (22.78)	$ (15.53)
Weighted-average shares used in computing net loss per share, basic and diluted	35,668,152	1,843,213	1,239,689

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, 2017	3,740,791	$ 7,154	922,622	$ —	$ 28	$ —	$ (5,021)	$ (4,993)
Issuance of Series A convertible preferred stock, net of issuance costs of $21 and value of convertible preferred stock liability of $891	3,156,784	7,186	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $88	8,880,462	54,912	—	—	—	—	—	—
Issuance of Series B convertible preferred stock in connection with license agreement	484,388	3,000	—	—	—	—	—	—
Issuance of common stock upon the exercise of stock options	—	—	114,225	—	43	—	—	43
Vesting of founder shares subject to repurchase	—	—	360,560	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	160,493	—	67	—	—	67
Stock-based compensation expense	—	—	—	—	151	—	—	151
Net Loss	—	—	—	—	—	—	(19,255)	(19,255)
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 restricted stock units	—	—	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

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

ARCUTIS BIOTHERAPEUTICS, INC.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2020	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (135,678)	$ (41,996)	$ (19,255)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	122	68	—
Non-cash lease expense	333	127	—
Net amortization/accretion on marketable securities	72	(354)	(14)
Stock-based compensation	7,943	824	151
Loss on disposal of property and equipment	42	—	—
Issuance of convertible preferred stock in connection with license agreement	—	—	3,000
Change in fair value of convertible preferred stock liability	—	—	(75)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,412)	(3,304)	243
Other assets	—	(47)	—
Accounts payable	5,674	(458)	1,264
Accrued liabilities	11,877	2,388	601
Operating lease liabilities	(6)	(84)	—
Net cash used in operating activities	(113,033)	(42,836)	(14,085)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of marketable securities	(279,103)	(60,830)	(11,532)
Proceeds from maturities of marketable securities	97,600	34,800	—
Purchases of property and equipment	(321)	(295)	—
Net cash used in investing activities	(181,824)	(26,325)	(11,532)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock upon exercise of stock options	526	265	386
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	94,239	61,207
Proceeds from initial public offering, net of issuance costs	168,642	—	—
Proceeds from issuance of common stock, net of issuance costs	128,360	—	—
Proceeds from issuance of common stock for ESPP purchase	617	—	—
Payment of financing costs	—	(1,401)	—
Net cash provided by financing activities	298,145	93,103	61,593
Net increase in cash, cash equivalents and restricted cash	3,288	23,942	35,976
Cash, cash equivalents and restricted cash at beginning of period	63,336	39,394	3,418
Cash, cash equivalents and restricted cash at end of period	$ 66,624	$ 63,336	$ 39,394
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:			
Conversion of preferred stock to common stock and APIC	$ 166,491	$ —	$ —
Reclassification of convertible preferred stock liability to Series A convertible preferred stock	$ —	$ —	$ 891
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 promise to treat immune-mediated dermatological diseases and conditions. The Company believes it has built the industry's leading platform for dermatologic product development. The Company's strategy is to focus on validated biological targets and to use our platform and deep dermatology expertise to develop differentiated products that have the potential to address the major shortcomings of existing therapies in its targeted indications. The Company believes this strategy uniquely positions it to rapidly advance its goal of bridging the treatment innovation gap in dermatology while maximizing its probability of technical success.

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

Initial Public Offering and Follow-On Financings

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

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

On February 5, 2021, the Company completed a public offering of 6,325,000 shares of stock at an offering price of $35.00 per share, including 825,000 shares sold pursuant to the underwriters full exercise of their option to purchase additional shares. The aggregate net proceeds received by the Company were approximately $207.4 million, after deducting underwriting discounts, commissions and estimated offering expenses. See Note 13.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $202.0 million and $66.3 million as of December 31, 2020 and 2019, respectively. The Company had cash, cash equivalents, restricted cash and marketable securities of $286.0 million and $101.3 million as of December 31, 2020 and 2019, respectively. In addition, on February 5, 2021, the Company received $180.3 million in net proceeds from an equity offering. See Note 13. Prior to selling common stock in its IPO and follow-on financings, the Company had historically financed its operations primarily through the sale of its convertible preferred stock. Management expects operating losses to continue for the foreseeable future.

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

Coronavirus Outbreak

In March 2020, the World Health Organization declared a pandemic related to the global novel coronavirus disease 2019 (COVID-19) outbreak. As of February 16, 2021, the Company's operations have not been significantly impacted by the COVID-19 pandemic. The Company is monitoring the impact COVID-19 may have on the clinical development of its product candidates, including potential delays or modifications to its ongoing and planned trials. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned clinical trials.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's 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.

Segments

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

Cash and Cash Equivalents

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

Restricted Cash

As of December 31, 2020, the Company held $1.5 million of restricted cash as collateral for a letter of credit related to our amended office space lease. As of December 31, 2019, the Company did not hold any restricted cash. See Note 7.

Marketable Securities

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

Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. Realized gains and losses as well as credit losses, if any, on marketable securities are included in other income, net. The Company evaluated the underlying credit quality and credit ratings of the issuers during the period. To date, no such credit losses have occurred or have been recorded. The cost of investments sold is based on the specific-identification method. As of December 31, 2020, there were net unrealized losses on marketable securities of $2,000, and as of December 31, 2019, there were net unrealized losses on marketable securities of $1,000. Unrealized gains and losses on marketable securities are reported as a component of accumulated other comprehensive loss on the balance sheets. Realized gains or losses on investments for the year ended December 31, 2020 were not material. There were no realized gains or losses on investments for the year ended December 31, 2019. Interest on marketable securities is included in other income, net.

Concentration of Credit Risk and Other Risks and Uncertainties

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

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

Fair Value Measurement

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

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

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

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

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

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, 2020 and 2019.

Leases

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

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

Preclinical and Clinical Accruals and Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical trials and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. For the years ended December 31, 2020, 2019 and 2018, 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 United States Congress enacted the 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 CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of COVID-19. The 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 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.

Emerging Growth Company Status

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

Recently Adopted Accounting Pronouncements

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

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

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

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 43,558	$ —	$ —	$ 43,558
Commercial paper	—	44,689	—	44,689
U.S. Treasury securities	13,018	—	—	13,018
Total assets	$ 56,576	$ 44,689	$ —	$ 101,265

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

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

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Notes to Financial Statements

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, 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.

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

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

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

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31, 2020	December 31, 2019
Prepaid clinical trial costs	$ 4,865	$ 2,998
Tax credits	510	145
Prepaid insurance	249	62
Deferred financing costs	—	1,747
Other prepaid expenses and current assets	1,219	257
Total prepaid expenses and other current assets	$ 6,843	$ 5,209

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Clinical trial accruals	$ 9,754	$ 1,497
Accrued compensation	4,434	1,379
Early exercise liability, current	176	225
Accrued expenses and other current liabilities	1,098	553
Total accrued liabilities	$ 15,462	$ 3,654

5. Property and Equipment, net

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

		December 31,	
	Useful life (in years)	2020	2019
Computer hardware	3	$ 286	$ 80
Furniture and fixtures	5	230	60
Construction in process		298	—
Leasehold improvements		1,280	155
Property and equipment, gross		2,094	295
Less accumulated depreciation		(78)	(68)
Property and equipment, net		$ 2,016	$ 227

Leasehold improvements are depreciated over the term of the lease. Depreciation expense was $122,000 and $68,000 for the years ended December 31, 2020 and 2019, respectively. There was no depreciation expense for the year ended December 31, 2018.

6. License Agreements

AstraZeneca License Agreement

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

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

There were no payments made or due in connection with AZ-Licensed Products for the year ended December 31, 2020. For the year ended December 31, 2019, the Company recorded research and development expense of $2.0 million related to the milestone payment made upon the completion of a Phase 2B study of ARQ-151 in plaque psoriasis for the achievement of positive Phase 2 data for an AZ-Licensed Product For the year ended December 31, 2018, the Company recorded research and development expense of $4.0 million related to the upfront fee payment and the issuance of Series B convertible preferred stock.

Hengrui Exclusive Option and License Agreement

In January 2018, the Company entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd. (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 year ended December 31, 2020.

Hawkeye Collaboration Agreement

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

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

7. Commitments and Contingencies

Operating Lease

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

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

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

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

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

	Amounts
2021	$ 114
2022	781
2023	965
2024	995
2025	1,024
Thereafter	2,794
Total minimum lease payments	$ 6,673
Less: Amounts representing interest	(1,709)
Present value of lease payments	$ 4,964
Operating lease liability, noncurrent	4,964
Total operating lease liability	$ 4,964

Straight-line rent expense recognized for operating leases was $602,000 and $151,000 for the years ended December 31, 2020 and 2019, respectively. Rent expense for the year ended December 31, 2018 was not material. 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 year ended December 31, 2020.

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

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

The following summarizes additional information related to the operating lease:

	December 31, 2020
Weighted-average remaining lease term (in years)	7.6
Weighted-average discount rate	7.0 %

Indemnification

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

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

Convertible Preferred Stock

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

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

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

In October 2019, the Company issued 8,122,963 shares of Series C convertible preferred stock at a purchase price of $11.63 per share for total net proceeds of $94.2 million, some of which were to related parties.

In September 2018, the Company issued 9,364,850 shares of Series B convertible preferred stock at a purchase price of $6.19 per share for total net proceeds of $54.9 million, some of which were to related parties.

In April 2017 and March 2018, the Company issued 3,590,845 and 3,156,784 shares, respectively, of Series A convertible preferred stock at a purchase price of $2.00 per share for net proceeds of $13.4 million. Additionally, in April 2017, the Company issued 149,946 shares of Series A convertible preferred stock as a result of the conversion of convertible promissory notes.

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, 2020, 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,	
	2020	2019
Convertible preferred stock outstanding	—	24,385,388
Options issued and outstanding	3,655,945	2,516,470
Common stock awards available for grant under employee benefit plans	2,501,329	1,550,150
Restricted stock units outstanding	162,930	—
Total common stock reserved	6,320,204	28,452,008

Authorized Share Capital

On February 4, 2020, the Company's certificate of incorporation was amended and restated to provide for 300,000,000 authorized shares of common stock with a par value of $0.0001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.0001 per share. There were no shares of preferred stock outstanding as of December 31, 2020 and 2019.

9. Stock-Based Compensation

In January 2020, the Company's board of directors approved the 2020 Equity Incentive Plan (2020 Plan), which became effective January 30, 2020 in connection with the IPO. The 2020 Plan serves as the successor incentive award plan to the Company's 2017 Equity Incentive Plan, (2017 Plan), and has 2,134,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit (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, lapsed or unexercised, and which following the effective date of the 2020 Plan are not issued under the 2017 Plan. In addition, the 2020 Plan reserve will increase on January 1, 2021 and each subsequent anniversary through 2030, by an amount equal to the lesser of (a) four percent of the shares of stock outstanding (on an as-converted basis) on the day immediately prior to the date of increase and (b) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 11,000,000 shares of stock may be issued upon the exercise of incentive stock options. Accordingly, on January 1, 2021, the plan reserve increased by 1,747,112 shares. As of December 31, 2020, the Company had 2,184,517 shares available for future grant under the 2020 Plan.

The 2020 Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company under terms and provisions established by the board of directors. Under the terms of the 2020 Plan, options may be granted at an exercise price not less than fair market value. The Company generally grants stock-based awards with service conditions. Options granted typically vest over a four-year period but may be granted with different vesting terms.

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

Stock Option Activity

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

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2017	472,991	$ 0.36	9.40	$ 360
Granted	836,992	0.64		
Exercised	(918,885)	0.42		
Balance—December 31, 2018	391,098	0.82	9.56	334
Granted	2,421,221	3.59		
Exercised	(250,865)	1.02		
Forfeited	(31,863)	0.58		
Expired	(13,121)	0.58		
Balance—December 31, 2019	2,516,470	3.47	9.44	7,673
Granted	1,368,825	26.83		
Exercised	(197,228)	2.67		
Forfeited	(32,122)	22.82		
Balance—December 31, 2020	3,655,945	12.09	8.78	59,274
Exercisable—12/31/2020[1]	2,034,061	7.33	8.54	42,314

(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, 2020. As of December 31, 2019, prior to the Company's IPO, the estimated fair value of the Company's common stock was determined by the board of directors.

The intrinsic value of options exercised for the year ended December 31, 2020 was $3.6 million.

The total grant-date fair value of the options vested during the year ended December 31, 2020 was $2.8 million. The weighted-average grant-date fair value of employee options granted during the year ended December 31, 2020 was $18.16.

Restricted Stock Unit Activity

The following table summarizes information regarding our RSUs:

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2019	—	—
Granted	163,560	$ 27.26
Vested	—	—
Forfeited	(630)	27.61
Unvested Balance—December 31, 2020	162,930	27.26

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,		
	2020	2019	2018
Research and development	$ 3,503	$ 351	$ 44
General and administrative	4,440	473	107
Total stock-based compensation expense	$ 7,943	$ 824	$ 151

As of December 31, 2020, there was $23.2 million of total unrecognized compensation cost related to unvested options that are expected to vest, which is expected to be recognized over a weighted-average period of 3.2 years. As of December 31, 2020, there was $3.6 million of total unrecognized compensation cost related to RSUs that is expected to vest, which is expected to be recognized over a weighted-average period of 3.6 years.

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

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

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

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

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

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

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,		
	2020	2019	2018
Expected term (in years)	5.5 – 6.8	5.1 – 6.6	5.9 – 6.1
Expected volatility	78.4 – 80.8%	68.6 – 72.5%	68.2 –72.4%
Risk-free interest rate	0.3 – 1.4%	1.6 – 2.6%	2.7 – 2.9%
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 $258,000 and $409,000 as a liability from the early exercise in the accompanying balance sheets as of December 31, 2020 and 2019, respectively. As of December 31, 2020 and 2019, there were $176,000 and $225,000 recorded in accrued liabilities, respectively, and $82,000 and $184,000 recorded in other long-term liabilities, respectively related to shares that were subject to repurchase.

Founder Awards

In August 2016, the Company issued 1,187,738 shares of restricted common stock to founders of which 1,102,903 shares vest under a service condition and 84,835 shares vest under a performance condition. The shares were issued under the terms of the respective restricted stock purchase agreements, or the Stock Purchase Agreement, and unvested shares 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 will vest on a monthly basis thereafter. In July 2018, performance conditions prescribed by the Stock Purchase Agreement were met and 84,835 shares of the restricted common stock were fully vested. As of December 31, 2019, 1,049,875 shares subject to the award had vested, and an additional 137,863 shares vested during the year ended December 31, 2020. As of December 31, 2020, all shares of restricted stock subject to the award had been vested.

2020 Employee Stock Purchase Plan

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

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

The Company commenced an offering period on January 31, 2020, which ended on May 31, 2020, and resulted in 19,862 shares of stock being issued under the ESPP. The Company also commenced an offering period on June 1, 2020, which ended on November 30, 2020, and resulted in 14,326 shares of stock being issued under the ESPP. In addition, the Company commenced an offering period on December 1, 2020, which will end on May 31, 2021. Stock-based compensation expense related to the ESPP was $346,000 for the year ended December 31, 2020.

10. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2020, 2019 and 2018. 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,		
	2020	2019	2018
Tax provision at U.S. statutory rate	$ (28,493)	$ (8,819)	$ (4,043)
State income taxes, net of federal benefit	(9,213)	(2,786)	(1,224)
Research and development tax and other credits	(2,413)	(655)	(265)
Change in valuation allowance	30,708	9,598	4,418
Uncertain tax positions	8,801	2,604	911
Permanent differences	616	58	219
Fair value adjustment	—	—	(16)
Other	(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, 2020	December 31, 2019
Deferred tax assets:		
Net operating loss carryforwards	$ 38,196	$ 11,457
Intangibles	1,777	1,937
Research and development tax credits	3,370	1,092
Accruals and reserves	1,041	355
Right-of-use liability	1,274	79
Stock-based compensation	1,122	62
Property and equipment	—	2
Gross deferred tax assets	$ 46,780	$ 14,984
Deferred tax liabilities:		
Property and equipment	$ (299)	$ —
Right-of-use asset	(859)	(68)
Gross deferred tax liabilities	$ (1,158)	$ (68)
Net deferred tax assets	$ 45,622	$ 14,916
Less valuation allowance	(45,622)	(14,916)
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 $30.7 million and $9.6 million during the years ended December 31, 2020 and 2019, respectively.

The Company has NOL carryforwards for federal, California and other state income tax purposes of approximately $180.7 million, $180.8 million and $3.2 million, respectively, as of December 31, 2020. 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 $177.2 million of NOLs generated after December 31, 2017 will be carried forward indefinitely.

On March 27, 2020, the CARES Act was signed into law in response to the economic challenges facing US 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, 2020, the Company also had federal and California research and development tax credit carryforwards of $6.4 million and $1.4 million, respectively. 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.

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 related to uncertain tax positions.

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

	Year Ended December 31,		
	2020	2019	2018
Beginning balance	$ 6,448	$ 2,241	$ 441
Increases related to tax positions taken during a prior year	5	4	—
Increases related to tax positions taken during the current year	13,821	4,203	1,800
Ending balance	$ 20,274	$ 6,448	$ 2,241

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

Income tax returns are filed in the U.S. and California. The Company is not currently under audit by the Internal Revenue Service or similar state or local authorities. The years 2016 and forward remain open to examination by the domestic taxing jurisdictions to which the Company is subject. 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 $20.3 million at December 31, 2020 was $16.7 million of tax benefits that, if recognized, would reduce our annual effective tax rate, subject to valuation allowance. We do not expect that there will be a significant change in the unrecognized tax benefits over the next 12 months.

We are 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, 2020, 2019 and 2018, we have not recognized any interest or penalties related to income taxes.

11. Net Loss Per Share

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

	As of December 31,		
	2020	2019	2018
Convertible preferred stock on an as-converted basis	—	24,385,388	16,262,425
Stock options to purchase common stock	3,655,945	2,516,470	391,098
Early exercised options subject to future vesting	339,385	621,053	644,166
RSU's subject to future vesting	162,930	—	—
ESPP shares subject to future issuance	3,733	—	—
Restricted stock subject to future vesting	—	137,863	413,589
Total	4,161,993	27,660,774	17,711,278

ARCUTIS BIOTHERAPEUTICS, INC.
Notes to Financial Statements

12. Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited financial information on a quarterly basis for 2020 and 2019. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
Year Ended December 31, 2020				
Total operating expenses	$ 28,651	$ 35,627	$ 38,303	$ 34,064
Other income, net	638	215	99	15
Net loss	(28,013)	(35,412)	(38,204)	(34,049)
Net loss per share, basic and diluted	$ (1.15)	$ (0.94)	$ (1.01)	$ (0.79)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
Year Ended December 31, 2019				
Total operating expenses	$ 6,952	$ 8,538	$ 14,648	$ 12,994
Other income, net	294	248	168	426
Net loss	(6,658)	(8,290)	(14,480)	(12,568)
Net loss per share, basic and diluted	$ (4.08)	$ (4.69)	$ (7.56)	$ (6.13)

13. Subsequent Event

On February 5, 2021, the Company completed a public offering of 6,325,000 shares of common stock at an offering price of $35.00 per share, which included 825,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, receiving approximately $207.4 million in aggregate net proceeds, after deducting underwriting discounts, commissions and estimated offering expenses.

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 16, 2021

By: /s/ Todd Franklin Watanabe
Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 16, 2021

By: /s/ John W. Smither
John W. Smither
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 Todd Franklin Watanabe and John W. Smither, 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 16, 2021
/s/ John W. Smither John W. Smither	Chief Financial Officer (Principal Accounting and Financial Officer)	February 16, 2021
/s/ Patrick J. Heron Patrick J. Heron	Director, Chairman	February 16, 2021
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri, Ph.D.	Director	February 16, 2021
/s/ Terrie Curran Terrie Curran	Director	February 16, 2021
/s/ Hallie E. Gilbert Hallie E. Gilbert	Director	February 16, 2021
/s/ Jonathan T. Silverstein Jonathan T. Silverstein, J.D.	Director	February 16, 2021
/s/ Ricky Sun Ricky Sun, Ph.D.	Director	February 16, 2021
/s/ Joseph Turner Joseph Turner	Director	February 16, 2021
/s/ Howard G. Welgus Howard G. Welgus, M.D.	Director	February 16, 2021

Exhibit 10.23

December 18, 2020

Matthew R. Moore
matthewrmoore@gmail.com

RE: Employment with Arcutis Biotherapeutics, Inc.
Dear Matt:

This employment letter sets forth the terms and confirms your employment as Senior Vice President and Chief Business Officer 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 11, 2021, 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 once COVID-19 related restrictions are lifted. 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 $365,000 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 of up to 40% of your base salary, based upon the achievement of both annual 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 Option. An option to purchase 160,000 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). Fifty percent (50%) of 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. Fifty percent (50%) of 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 of the Advisory Agreement by and between the Company and you (namely July 20, 2020) 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 Stock Option. An option to purchase 25,000 shares of the Company's common stock (the "Performance Based 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 e date of grant. The shares subject to the Stock Option will vest and become exercisable as follows:

1) Upon the conclusion of a deal to out-license roflumilast in Japan, 12,500 options will commence vesting at a rate of 2.0833% per month so long as you remain employed by the Company through the applicable vesting date; and

2) Upon conclusion of a deal for another major geography (e.g., China or Europe), 12,500 options will commence vesting at a rate of 2.0833% per month so long as you remain employed by the Company through the applicable vesting date; or

3) Upon conclusion of a global ex-U.S. deal, 25,000 options will commence vesting at a rate of 2.0833% per month so long as you remain employed by the Company through the applicable vesting date.

For purposes of clarity, no more than 25,000 Performance-Based Stock Options will be available to you per this section 1 (C) (ii).

The Stock Options and Performance-Based Stock Options will otherwise be subject to the terms and conditions of the Company's 2020 Equity Incentive Plan (the "Plan") and a stock option agreement and/or performance-based stock option 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.

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.

b) The Company will reimburse Employee for actual expenses, as evidenced by receipts, incurred for travel to and from and housing at the corporate headquarters, up to a maximum of $5,000 per month. No other reimbursement will be made for these costs.

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 San Francisco 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 18, 2020. 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,

By: /s/Todd Franklin Watanabe
Name: Todd Franklin Watanabe
Title: Chief Executive Officer
Date: December 18, 2020

ACCEPTED AND AGREED:

By: /s/ Matthew R. Moore
Name: Matthew R. Moore
Title: Senior Vice President and Chief Business Officer
Date: January 6, 2021

Arcutis Biotherapeutics, Inc.
Severance & Change in Control Agreement

This Severance & Change in Control Agreement (the "**Agreement**"), is entered into by and between Matthew R. Moore (the "**Executive**") and Arcutis Biotherapeutics, Inc., a Delaware (the "**Company**"), and is effective as of the date that Executive commences employment with the Company (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.

ARCUTIS BIOTHERAPEUTICS, INC.

EXECUTIVE

/s/ Matthew R. Moore

Matthew R. Moore

Date: February 16, 2021

/s/ Frank Watanabe

By: Frank Watanabe

Title: President and Chief Executive Officer

Date: February 9, 2021

[Signature Page to the Severance & Change in Control Agreement]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

SUPPLY AGREEMENT

This Supply Agreement (hereinafter referred to as the **"Agreement"**) is entered into on the 24th of November, 2020 (hereinafter referred to as **"Effective Date"**)

Between:

a) **Arcutis Biotherapeutics, Inc.** (hereinafter referred to as the **"Company"**), a company incorporated and registered in the USA, located at 3027 Townsgate Rd Suite 300, Westlake Village, CA 91361, the USA, holder of Tax identification Number 81-2974255.

b) **Interquim, S.A.** (sole shareholder company) (hereinafter referred to as **"Interquim"**), a company incorporated and registered in Spain, located at C/ Joan Buscallà 10, 08173, Sant Cugat del Vallès (Barcelona), Spain, holder of Tax identification Number A-08536476.

The Company and Interquim are hereinafter referred to collectively as the "Parties" and individually as a "Party".

TAKING INTO CONSIDERATION:

I. That Interquim is engaged in the manufacture and supply of the active pharmaceutical ingredient **Roflumilast** (as defined below) and has the adequate technology necessary for its manufacturing, as well as its Drug Master File; and

II. That the Company is desirous of being supplied with Roflumilast during the duration of this Agreement, to use it as Active Pharmaceutical Ingredient (as defined below) in medicinal products to be used as a treatment for diseases in humans, including without limitation, skin diseases (including the End Product, as defined below), manufactured by or on behalf of the Company for sale in the Territory (as defined below), and Interquim is willing to sell Roflumilast through Interquim's agent Ren-Pharm for that purpose to the Company upon the terms and conditions herein set forth;

NOW THEREFORE, the Parties agree the following:

Article 1 - Definitions

In this Agreement the following terms and expressions have the following meaning it being understood that words denoting the singular include the plural and vice versa, all of it unless the context otherwise requires.

1.1 "Active Pharmaceutical Ingredient" or "API" or "Substance" means Roflumilast, as stated in Annex I.

1.2 "Affiliate" means with respect to either Party any person, partnership, company or other entity which, directly or indirectly, Controls, is Controlled by or is under common Control with such Party. "Control" means direct or indirect ownership or control of more than 50% (fifty percent) of the voting stock.

"current Affiliates" means entities regarded as Affiliates according to Article 1.2 of this Agreement on the Effective Date.

1.3 "ARQ-151" means topical roflumilast cream developed by Arcutis Biotherapeutics, Inc. as Final Drug Product.

1.4 "Company": means Arcutis Biotherapeutics, Inc. and its current Affiliates, where applicable.

1.5 "Final Drug Products" means any finished medicinal products for clinical use and pending successful trial, for commercial use as a treatment for diseases in humans, including without limitation, skin diseases, manufactured or have manufactured by the Company and containing the Substance.

1.6 "Facility" means the manufacturing facility of Interquim or its Affiliate where the Substance is manufactured.

1.7 GMP" or "cGMP" means the current Good Manufacturing Practices, as amended from time to time, as currently notably defined in ICH Q7 "Good Manufacturing Practices for Active Pharmaceutical Ingredients", the ICH-guidelines "Guidance for Industry, Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients", the US "Code of Federal Regulations, Title 21: Part 11, 210 and 211 Current Good Manufacturing Practice" and EU GMP Guide Part II "Basic requirements for Active Substances used as Starting Materials" including its Annexes and other quality related regulations applicable to the Substance, all as amended from time to time.

1.8 "Initial Term": means a period beginning on the Effective Date of this Agreement and ending 5-years thereafter, provided however, that if the NDA for ARQ-151 is not approved by FDA by [***], then this Initial Term will be extended for a period of time equal to the number of days after [***] until such FDA approval.

1.9 "Interquim" or "Supplier": means Interquim, S.A. (sole shareholder company) and its current Affiliates, where applicable.

1.10 "Specifications" means the specifications for the Substance as set forth in Annex II.

1.11 "Regulatory Authority" means any regulatory or governmental authority, competent for approvals, licenses, registrations, marketing authorizations, reimbursement decisions, variations and/or safety issues with respect to the Substance and/or medicinal products, including the Final Drug Products.

1.12 "Renewal": means a period of one (1) year as of the expiry of the Initial Term or the preceding Renewal;

1.13 "Territory": means worldwide.

1.14 "Third Party": means any person or entity other than Interquim or the Company.

1.15 "Reference Standards" - specific reagents, reference standards, impurity standards, or other product specific materials necessary for testing and evaluation of API in the Substance state through Final Drug Product. This includes API and impurity standards.

Article 2 – MANUFACTURE, SUPPLY AND DELIVERY

2.1 Supply and Purchase Obligations. Pursuant to the terms hereof, Interquim shall manufacture and supply API to the Company. During the Initial Term of this Agreement, the Company shall purchase a minimum of 90% of its annual API requirements to be used for the Company's Final Drug Products from Interquim. Interquim shall manufacture and supply the API to the Company given the forecasted quantities in the agreed upon lead time. All API to be supplied under this Supply Agreement shall be manufactured by Interquim in conformance with Specifications, Applicable Laws, and cGMPs. If Interquim fails to deliver the Product ordered and confirmed with a PO within [***] days of the confirmed delivery date (excluding force majeure) in accordance with Articles 2 and 4, the Company shall be relieved of any obligation hereunder to purchase any portion of Arcutis' requirements from Interquim until the Substance not delivered by Interquim is received, except in those cases previously agreed by the Parties. Company shall notify Interquim of order(s) from other suppliers in the event of such circumstance within [***] ([***]) business days of placing the order(s).

2.2 For the avoidance of doubt, it is clarified that Interquim may only supply the API, either by itself or through its Affiliates, to Third Parties for sale into the Territory, if and only if, such Third Parties do not use the API in a final drug product for topical use, during the Initial Term of this Agreement and any subsequent renewal periods.

Upon request of Interquim with [***] days in advance, the Company shall send to Interquim the Company's statement of Substance consumption in order to verify it with Interquim's internal records.

2.3 Interquim shall supply the API according to the Specifications and quality standard requirements as stated in the Quality Agreement. This Quality Agreement shall prevail over this Supply Agreement exclusively for technical and/or quality matters.

2.4. A Joint Steering Committee shall be formed within 30 days of Effective Date. The Joint Steering Committee will meet quarterly to review performance. To the extent that there are any performance issues, escalation will be made to an Executive Steering Committee comprised of, at a minimum, respective Heads of Operations and Heads of Quality for both Parties. If Substance fails to meet established Quality requirements for [***], escalation may occur. If no reasonable, mutually agreeable plan for corrective action is presented by Interquim within [***] from escalation to the Executive Steering Committee, Company may elect to move supply to an alternate API manufacturer without penalty.

Article 3 - Prices and Payment

3.1 For each delivery of Substance, Company shall pay to Interquim a supply price which is indicated in Annex 1. This supply price is a supply price for delivery CIP (Incoterms 2020). The Substance included in each firm purchase order shall remain under the full property of Interquim until the Company has totally paid the corresponding invoice. Interquim shall have the right to suspend the performance of its obligations under this Agreement in the event any invoice issued by Interquim to the Company (which is not being disputed in good faith) is not satisfied by the Company according to the terms and conditions of this Agreement.

3.2 After the Initial Term of the Agreement, the Parties may at their sole discretion discuss a supply price adjustment. In this event, Parties will negotiate in good faith and may mutually agree on a new supply price for any subsequent purchase orders of the Substance. Any supply price adjustment must be reasonably justified. Should the Parties be unable to agree in writing on new price terms, this Agreement shall be extended per Section 12.1 according to the terms presented herewith, with Arcutis' annual volume commitment being revised to a minimum of 60% of the total annual forecasted volume for API, all other terms remaining the same.

3.3 For each delivery of Substance, Interquim shall send an invoice to either the address given by the Company on the purchase order, or to Company's Accounts Payable email address <[***]>, stating the amount due (including any applicable VAT). Company shall pay to Interquim the total amount, stated in Interquim's invoice by bank transfer within [***] ([***]) calendar days from the invoice issuance date, to the following Interquim's bank account:

Name: INTERQUIM
Bank: BANCO BILBAO VIZCAYA ARGENTARIA, S.A IBAN Nr.: [***]

Article 4 - Forecasting and Orders

4.1 **Forecast.** In order to enable Interquim to dispatch all the purchase orders punctually, the Company will give Interquim [***] non-binding Rolling Forecast of estimates of its requirements for Substance on a quarterly basis and at least [***] ([***]) days prior to the beginning of each subsequent calendar quarter. [***] of each Rolling Forecast shall be binding. [***] of each Rolling Forecast are non-binding and serve only to facilitate Interquim's production scheduling.

Purchase Orders. Prior to the beginning of each calendar month starting on a mutually agreed upon date, Company shall submit a firm order "Firm PO" to Interquim for quantities of Substance to be delivered during the month which commences at least [***] ([***]) days from the date of the Firm PO. Interquim shall accept and fulfill all orders for API that are consistent with the most recent prior Rolling Forecast for the relevant quarter provided by Company in accordance with the terms of the Agreement. To the extent a Firm PO for any calendar quarter exceeds 100% of the most recent prior Rolling Forecast for the relevant quarter, Interquim shall use commercially reasonable efforts to manufacture and supply the quantity ordered over 100%.

4.2 **Order Quantities.** Interquim shall submit a proposal on batch size to scale the process for approval by the Company. It is expected that this scaled batch size will be [***], with a subsequent scale-up to[***]. Company's approval shall not be unreasonably withheld. [***].

4.3 **Confirmation of purchase orders.** Each purchase order shall be in writing, and shall specify the quantity ordered, the price, the place of delivery and the required delivery date, which shall allow [***] ([***]) days after the confirmation by Interquim of such purchase order. Interquim shall, within [***] ([***]) business days of receipt of a purchase order, accept such order and confirm to the Company the delivery dates, provided that:

(i) with such order, the Company is not exceeding [***] percent ([***]%) of the quantities for the relevant quarter forecasted according to the last forecast.

Notwithstanding the foregoing, Interquim shall use its commercially reasonable efforts to manufacture and supply to the Company any quantities of Substance pursuant to its purchase orders in excess of [***] percent ([***]%) of the quantity forecasted for the applicable quarter in the most recent prior forecast.

(ii) the proposed delivery date is in line with delivery times stated in this Agreement.

(iii) the ordered quantities are in line with the applicable order quantities as stated in Section 4.2.

(iv) the order is placed for the agreed Supply Price.

For the avoidance of doubt, no purchase order shall be deemed accepted unless express confirmation in writing by Interquim to the Company or unless [***] ([***]) business days pass after Interquim's receipt of a purchase order from Company without a proper rejection from Interquim in accordance with the terms of this Agreement.

4.4 **Changes of confirmed purchase orders.** Interquim shall be free to accept or reject changes requested by Company in already confirmed purchase orders (e.g. quantities). Where Interquim accepts such changes in already confirmed purchase orders, Interquim may consider such changed orders as new orders subject to new delivery times, provided, however that Interquim notifies Company in writing as such within [***] ([***]) business days upon acceptance of such changed order.

4.5 **Cancellation of confirmed purchase orders.** Company acknowledges that a confirmed purchase order is an obligation as per this Agreement. Hence Interquim shall only accept the cancellation of a confirmed order provided that the Company cancels more than [***] days prior to the date of scheduled production and compensates Interquim for the cost of raw materials, to the extent such raw materials can not be used for a future order.

4.6 The provisions of this Agreement shall prevail if the terms stated in the Company's purchase order are inconsistent with or differ from these provisions.

Article 5 – Delivery

5.1 Delivery of API results in full payment of the agreed Supply Price. Delivery of Substance to the Company shall be made CIP at Company's direction (Incoterms 2020).

5.2 Shelf life of the Substance. The Substance shall have at least [***] ([***]) of residual shelf life on the date on which delivery of the Substance takes place. Where applicable, Interquim will support requalification to extend the expiry of such Substance.

5.3 Security stock. Interquim, at its sole cost and expense, shall at all times maintain a security stock equivalent [***] months of Substance (to be determined annually in good faith by the parties) with at least [***] ([***]) of residual shelf life. The security stock levels may be adjusted at any time upon agreement of both parties. Company may receive a shipment of the security stock from Interquim upon written request. After receipt of such written request accompanied by a PO, Interquim will make best efforts to ship the Substance from the security stock within [***] ([***]) business days.

5.4 Supplier to implement and allow Arcutis to review a business continuity plan detailing strategy for responses to and recovery from potential disruptive events within [***] ([***]) months of the effective date of this Agreement. [***].

5.5 With each delivery of Substance, Interquim shall provide to the Company the delivery documents agreed with the Company in writing.

5.6 The Company shall follow proper use, handling, storage, inspection, maintenance and disposal practices with respect to Substance and in compliance with the applicable legal requirements and standards. The Company also undertakes to observe all reasonable precautions and instructions provided in writing by Interquim.

5.7 If for any reason not attributable to Interquim, the Company instructs Interquim not to ship the Substance already manufactured or otherwise refuses to take delivery of shipped Substance (pursuant to a Company's confirmed purchase order), Interquim in addition to its other rights shall be entitled to charge a storage, handling and retention charges from the Company on account of such refusal.

5.8 Delivery of Reference Standards. Reference Standards shall have the maximum shelf life at the time of delivery. In any case, Interquim shall support requalification to extend the expiry of such Reference Standards.

Article 6 - Delivery Controls

6.1 Interquim shall test, inspect and release each lot of Substance against the specification. Interquim to provide certificate of analysis and certificate of compliance, as described in Section 6.2. The Company may test and inspect Substance and either accept or reject if it does not comply with Specifications by providing notice to Supplier within [***] days of delivery or within [***] days of discovery of latent defect.

6.2 In the event a given delivery of Substance supplied by Interquim fails to comply with the agreed quality standards within its shelf life and if Interquim agrees in its reasonable and good faith discretion, the Company shall dispose of the Substance in accordance with Interquim's reasonable instructions at Interquim's cost and expense. Interquim shall replace at Interquim's own cost the defective quantities of Substance by a new delivery of Substance meeting the agreed quality standards; provided that the Company allows Interquim a reasonable period of time in which to evaluate the defect and Interquim agrees, in its reasonable and good faith discretion, that such delivery of Substance is defective. Interquim's liability under this Article 6 is limited to the replacement of the Defective Substance.

If Interquim, in its reasonable and good faith discretion, disputes that the Substance fails to comply with the Specifications, the disputed facts shall be finally determined by a mutually acceptable expert. In that case Interquim and the Company shall submit to the expert a sufficient number of samples of each production batch of such Substance for analysis. Such expert shall be chosen by the Parties within [***] days upon request by either Party.[***]. The expert's decision will be definitive (absent manifest errors or gross negligence of such expert in assessing the matter).

Quality Agreement. Within [***] ([***]) days of signing this Agreement,the Parties shall enter into an agreement specifying the Parties' respective responsibilities for storage, release, stability, vigilance program, quality control, and quality assurance with respect to the Active Ingredient (the Quality Agreement). In the event there are conflicts between the terms of this Agreement and the Quality Agreement, the Quality Agreement will prevail.

Quality Control Requirements. Quality Control Requirements shall mean that Interquim shall subject all Active Pharmaceutical Ingredient to quality control inspections using quality control procedures, specifications, and systems to assure strict compliance with the Specifications and absence of defects.

Drug Master File ("DMF"). Interquim shall provide the appropriate authorizations to each applicable Governmental Authority allowing Company the right to reference all Drug Master Files to apply for, obtain and maintain any Market Authorization Approval or other regulatory approvals for the Product. Interquim shall correct any deficiencies of such Drug Master File identified by any Governmental Authority in a prompt and efficient manner so as to prevent any delay in Company obtaining regulatory approval for a Final Product. In addition, Interquim shall be responsible for maintaining such Drug Master File in accordance with all Applicable Laws and ensuring that all data and information incorporated therein is accurate and current as necessary to support obtaining and maintaining the applicable Market Authorization Approvals and regulatory filings by Company.

Active Pharmaceutical Ingredient Release. No Active Pharmaceutical Ingredient shall be released to Company without a Certificate of Analysis and Certificate of cGMP Compliance, both of which shall be supplied to Company by Interquim, (a) stating that the Active Pharmaceutical Ingredient being shipped has been tested and conforms to the Specifications and Quality Control Requirements, (b) confirming compliance with cGMP, the FD&C Act and all other Applicable Laws, rules, and regulations.

Delivery Terms. Shipment of the API will be to a location according to the incoterm chosen by the Parties, which shall also regulate the payment of carrier, freight charges, title and risk of loss. The API will be shipped with the requisite packing slip, Certificates of Analysis, and Certificate of cGMP Compliance.

Interquim shall promptly notify Arcutis (within a maximum of ten working days) of any regulatory or cGMP violations (e.g. FDA Warning Letter or suspension/withdrawal of one or more CEPs or critical and major findings) identified during authority cGMP inspections and impacting the quality of Roflumilast intended to be shipped to the Company and/or potentially affecting the ability of Interquim to produce or ship Roflumilast, and shall co-operate with the Company in the scheduling of any planned inspection concerning Roflumilast.

Changes in Manufacturing Processes. Changes should be evaluated and communicated based upon the potential regulatory and quality impact to allow the Company to implement such changes in its regulatory documentation if a regulatory approval is needed before the implementation.

Interquim shall not make any changes in the manufacturing processes of the API except as required by Applicable Laws or those which do not require regulatory approval before its implementation without Company's prior consent. Interquim shall provide Company with not less than [***] ([***]) months' prior written notice of Interquim's implementation of any intended significant material change(s) to its manufacturing processes for the Active Pharmaceutical Ingredient, which might affect the quality of the Active Pharmaceutical Ingredient or any Market Authorization Approvals for the Product ("Change Notice") (e.g. any change in the Active Pharmaceutical Ingredient Specifications or Packaging Specifications made by Interquim other than pursuant to a Company request). If a significant change is implemented by Interquim and Company provides Interquim with demonstrable evidence that the utility (i.e. the conditions of being useful as a pharmaceutical product in connection with the manufacture and performance of the Product) of the Active Ingredient is significantly altered in that there is no similar bioequivalence (to Active Pharmaceutical Ingredient before the significant change) or similar Product specifications when formulated in the final Product formulation (together, "Utility Loss"), the parties shall exert their reasonable commercial efforts to resolve issues related to the Utility Loss in order to continue operating under this Agreement. Until the Utility Loss issue is resolved, Company may purchase API from other supplier(s). In the case of pending specification change, Interquim shall allow Company [***] ([***]) days to purchase Active Pharmaceutical Ingredient supply needed prior to the implementation of specification changes. Company shall, over the course of the notice period, have the right to place POs and Interquim shall have the obligation to accept such POs and manufacture up to [***] ([***]) times the quantity of API reflected in the Rolling Forecast (as defined below).

6.3 Notices. Each Party shall notify the other of any information, whether received directly or indirectly, which might affect the marketability, safety, of effectiveness of Final Product which was manufactured using Active Pharmaceutical Ingredient supplied by Interquim hereunder an/or which might result in the Recall or seizure of the Final Product which was manufactured using Active Pharmaceutical Ingredient supplied by Interquim hereunder. For purposes of this Agreement, a "Recall" shall mean any action (i) to recover title to or possession of quantities of the Final Product which was manufactured using Active Pharmaceutical Ingredient supplied by Interquim hereunder sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of such Product which was manufactured using Active Pharmaceutical Ingredient supplied by Interquim hereunder from the market) or (ii) by any Governmental Authority to detain or destroy any of such Final Product which was manufactured using Active Pharmaceutical Ingredient supplied by Interquim.

Whenever a recall of any Substance in the Territory is being contemplated for any reason, each party shall, without prejudice to its obligations under any governmental regulation in the Territory, promptly consult with the other with the view to deciding the appropriate action to take with respect thereto. Without derogating from the foregoing, the Company shall follow all reasonable instructions of Interquim, and Interquim shall follow all reasonable instructions of the Company, with regard to recall of the Final Drug Product.

The costs and expenses directly related to any recall and/or withdrawal of the Substance which is primarily due to acts or omissions on the part of the Company shall be borne by the Company. The costs and expenses directly related to any recall and/or withdrawal of the Substance which is primarily due to acts or omissions on the part of Interquim shall be borne by Interquim. Costs and expenses directly related to any recall and/or withdrawal of the Substance which is primarily due to governmental or regulatory act or intervention or to causes independent of the Parties shall be equally shared by Interquim and the Company.

Article 7 - Quality, Warranties, Insurance

7.1 Interquim shall manufacture the Substance (i) in accordance with the production process, as described in the DMF (the "Production Process") (ii) for use as active pharmaceutical ingredient in End Products and (iii) using Interquim's established GMP/cGMP systems, approved and certified by EMA (European

medicines agency) and FDA (US Food and Drug Administration). In the event that any other approval/certification is required by the Company, the Parties shall negotiate in good faith on the applicable terms and conditions, including but not limited to cost bearing.

7.2 The Substance (a) shall comply with the Specifications; (b) shall be manufactured according to (i) this Agreement, (ii) all applicable GMP and cGMP requirements, (iii) the Production Process, (iv) the terms and Specifications of the respective certificate(s) of analysis, (v) ICH Guidelines and all other Applicable Laws, rules, and regulations.

7.3 Each Party ("Representing and Warranting Party") represents and warrants to the other Party that as of the date hereof and of the Effective Date of this Agreement:

(a) ORGANIZATION. The Representing and Warranting Party is a company duly organized, existing and in good standing, under the laws of its country of registration, as indicated in the beginning of this Agreement.

(b) POWER, AUTHORITY AND ENFORCEABILITY. The Representing and Warranting Party has full legal and corporate power and authority to enter into and perform this Agreement. This Agreement has been duly executed and delivered by duly authorized signatories of the Representing and Warranting Party. This Agreement is a valid and binding obligation of the Representing and Warranting Party, enforceable against the Representing and Warranting Party in accordance with its respective terms.

(c) COMPLIANCE WITH LAW. The Representing and Warranting Party and its activities under this Agreement, will be in compliance in all respects with any and all applicable law (statutory, judicial or otherwise), ordinances, regulations, judgments, orders, directives, injunctions, writs, decrees or awards of any governmental authority, valid in the Territory.

(d) CONSENTS. Except as otherwise provided in this Agreement, no consent, authorization, order or approval of, or filing or registration with, any governmental authority or other Person is required for the execution and delivery by the Representing and Warranting Party of this Agreement and the consummation by the Representing and Warranting Party of the transaction contemplated by this Agreement.

(e) NO VIOLATION. Neither the execution and delivery of this Agreement by the Representing and Warranting Party, as the case may be, nor the consummation by the Representing and Warranting Party of the transaction contemplated, will conflict with or result in a breach of any of the terms, conditions or provisions of any governing or charter document, or of any statute or administrative regulation, or of any order, writ, injunction, judgment or decree of any court or governmental authority or of any arbitration award or any agreement binding upon the Representing and Warranting Party or its assets.

(f) NO DEFAULT. The Representing and Warranting Party is not a party to any unexpired, undischarged or unsatisfied written or oral contract, agreement, indenture, mortgage, debenture, note or other instrument under the terms of which performance by the Representing and Warranting Party according to the terms of this Agreement will be a default, or whereby timely performance by the Representing and Warranting Party according to the terms of this Agreement may be prohibited, prevented or delayed.

(g) LITIGATION. There is no action or proceeding pending or, to the knowledge of the Representing and Warranting Party, threatened against the Representing and Warranting Party before any court, arbitrator, administrative agency or other tribunal which could have a material adverse impact upon the Representing and Warranting Party's right, power and authority to enter into this Agreement, to receive the rights granted to the Representing and Warranting Party, to grant the rights granted to the other Party or to otherwise carry out its obligations.

7.4 Each Party shall assume all risks associated with its, any of its associates' (including entitled but not limited to affiliates, licensees, sub-licensees, agents etc.) and/or, any of its representative's acts and omissions under or otherwise in connection with this Agreement, including in relation to any breach of its covenants, representations and warranties and/or its negligence or willful misconduct. Each Party will maintain liability insurance covering its respective risks, with reputable and financially secure insurance carriers or a program of self-insurance as are appropriate and in accordance with applicable legal requirements, sound business practice and its respective direct and contingent obligations under this Agreement, in each case with limits of not less than [***] US dollars ($[***]) per occurrence and in the aggregate. If requested, a Party shall deliver to the other Party appropriate evidence that such liabilities are adequately covered.

7.5. Qualified Personnel. Interquim shall engage and employ only professionally qualified personnel to perform the services contemplated hereunder. Interquim further represents and warrants that neither it nor any of its employees is, or is reasonably likely to become (based on a conviction by the courts or a finding of fault by any applicable regulatory authority): (a) debarred pursuant to the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a), as amended from time to time; (b) disqualified from participating in clinical trials pursuant to 21 C.F.R.§312.70, as amended from time to time; (c) disqualified as a testing facility under 21 C.F.R. Part 58, Subpart K, as amended from time to time; (d) excluded, debarred or suspended from or otherwise ineligible to participate in a "Federal Health Care Program" as defined in 42 U.S.C. 1320a-7b(f), as amended from time to time, or any other governmental payment, procurement or non-procurement program; or (e) included on the HHS/OIG List of Excluded Individuals/Entities, the General Services Administration's List of Parties Excluded from Federal Programs, or the FDA Debarment List. Interquim shall notify Company immediately if any of the foregoing is not true for any reason at any time. Interquim represents and warrants that it shall not hire or retain as an officer or employee any Person who has been convicted of a misdemeanor or felony under the laws of the United States relating to the regulation of any drug product by the FD&C Act or relating to the regulation of any federal healthcare program by the U.S. Department of Health and Human Services. If at any time a representation and warranty in this Section 7.5 is no longer accurate, Interquim shall immediately notify Company of such fact.

7.6. Active Pharmaceutical Ingredient. The Active Pharmaceutical Ingredient, at the time of sale and shipment to Company by Interquim, (a) will conform to the Specifications, as then in effect, (b) will have dating until re- evaluation of not less than that which is set forth in Section 5.2 above, (c) will have been manufactured in all material respects in accordance with cGMP in effect at the time of manufacture, (d) will not be adulterated or misbranded within the meaning of the FD&C Act, (e) will not have been manufactured, sold or shipped in violation of any Applicable Laws in any material respect, (f) will be conveyed with good title, free and clear of all security interests, liens or encumbrances, and (g) as may be appropriate or applicable, will have been approved by any and all requisite governmental and regulatory authorities.

Article 8 – Liability and Indemnity

8.1 Except as otherwise specifically provided for in this Agreement, Interquim shall indemnify, compensate and hold harmless the Company and its respective directors, officers and employees from and against any claim, action, liability, loss, damages, costs and expenses (including reasonable attorneys' fees) (hereinafter collectively referred to as "Damages"), incurred by or rendered against the Company or any of its directors, officers, agents, contractors and employees which result from or arise out of Interquim's material breach of this Agreement and/or any wilful misconduct (*dolo*) or negligence of Interquim, provided, however and only to the extent that such Damages have not been caused by the negligence or wilful misconduct of the Company or a breach of the Company's warranties or representations or obligations under or in connection with this Agreement.

8.2 Except as otherwise specifically provided for in this Agreement, the Company shall indemnify, compensate and hold harmless Interquim and its respective directors, officers and employees from any Damages incurred by or rendered against Interquim or any of its directors, officers and employees which result from or arise out of either (a) the negligence or willful misconduct (*dolo*) of the Company;
(b) Company's activities performed under this Agreement and/or Company's breach of this Agreement or any individual purchase order; (c) Company's breach of any statutory/legal obligations; (d) any injury or death of any person, and loss of or damage to property in any way caused by the promotion, use or sale of End Products by the Company; or (e) an infringement of third party intellectual property rights caused by the End Products (as further provided for in Article 10); except in each case to the extent that such Damages result from the negligence or wilful misconduct (*dolo*) of Interquim or a material breach of Interquim's warranties or representations or obligations under or in connection with this Agreement.

8.3 Each Party shall notify the other Party of any claim, action or demand being made against the notifying Party in respect of any matter for which the other Party is or may be liable hereunder ("Indemnity Claim"). The Parties agree to render each other reasonable assistance in the defense of any claim, action or demand made hereunder.

8.4 For the avoidance of doubt, neither Party shall be liable to the other Party and/or its respective directors, officers and employees for all and any: loss of business earnings, loss of anticipated sales, loss of profits, loss of the chance to make profit, loss of reputation or goodwill, loss of data or documentation, loss of opportunity, punitive damages, indirect, special or consequential damages. Nothing in this Agreement shall limit or exclude either Party's liability in case of (i) death, personal injury; (ii) fraudulent misrepresentation, criminal acts or the tort of deceit, gross negligence or willful misconduct (*dolo*) or (iii) where such a limitation or exclusion would be contrary to applicable law.

Article 9 - Confidentiality

9.1 Confidentiality of information disclosed by or on behalf of one of the Parties hereto or any of its Affiliates (the “Disclosing Party”) to the other Party or any of its Affiliates (the “Receiving Party”) is governed by this Article 9.

9.2 All information, data and documents regarding the Substance, the End Products, and any other information, data, and documents disclosed by the Disclosing Party to the Receiving Party relating to the Disclosing Party’s business pursuant to or in connection with this Agreement which is marked as “confidential” or the like or which should be reasonably understood to be confidential (the “Confidential Information”) is deemed strictly secret and confidential.

Unless any written consent by the Disclosing Party or written agreement between the Parties provides otherwise, the Receiving Party must treat such Confidential Information as it would treat its own proprietary information, but shall apply in any event at least such degree of care as a diligent person would. The Receiving Party may not divulge or otherwise disclose such Confidential Information to any third party. The Receiving Party undertakes and ensures that such Confidential Information is not used for any purpose other than that set forth in this Agreement.

Confidential Information shall not include any information, data and documents that, as evidenced by competent proof:

(a) is generally known to the public at the time of, or after disclosure hereunder becomes generally known to the public through no breach of this Agreement by or any fault of the Receiving Party, or

(b) was already known to the Receiving Party or any of its Affiliates prior to disclosure by the Disclosing Party, as evidenced by means generally accepted in law, provided that such information, data or documents was not acquired/obtained directly or indirectly from the Disclosing Party or any of its Affiliates; or

(c) was or is provided in good faith to the Receiving Party or any of its Affiliates by an independent third party, provided that such third party had lawfully acquired/obtained the information, data or documents and has the lawful right to disclose it without obligation of confidentiality, as evidenced by means generally accepted in law; or

(d) was or is developed by or for the Receiving Party or any of its Affiliates independently of, and without reference to, any of the Confidential Information, as evidenced by means generally accepted in law.

9.3 The Parties may disclose, on a need-to-know basis, Confidential Information to their respective Affiliates, officers, directors, employees, consultants, and those of their respective Affiliates (“Related Parties”) and, the Company or any of its Affiliates, in addition may also disclose (having informed Interquim in advance) Confidential Information to Regulatory Authorities provided that (i) each Party shall be liable to the other for the non-fulfillment of such Related Parties' confidentiality obligations and
(ii) further provided that such Related Parties are bound by confidentiality and non-use obligations materially not less stringent than those set forth by this Article 9, which confidentiality and non-use obligations shall remain in force during the term this Agreement is in effect and thereafter, for as long as the Confidential Information is not part of the public domain by reasons other than by unauthorized act or omission by any Party (including its Affiliates and Related Parties).

9.4 If the Receiving Party is required to disclose Confidential Information by an order of a competent court or administrative agency or by law, the Receiving Party shall be permitted to disclose Confidential Information to the extent required; provided, however, that the Receiving Party shall provide the Disclosing Party with notice of its intent to disclose such information in order to provide the Disclosing Party with the opportunity to safeguard such information. In the event that it is not possible to prevent such disclosure or the disclosure is not prevented for any reason whatsoever, the Receiving Party undertakes to disclose only that portion of the Confidential Information that is legally required to be disclosed.

9.5 Any Confidential Information exchanged between the Parties prior to the Effective Date shall be treated as Confidential Information pursuant to this Art. 9.

Article 10 – Intellectual Property

10.1 Each Party shall retain all property rights in know-how, patents and other intellectual property as well as in trade secrets owned by such Party prior to this cooperation or developed independently during the duration of this Agreement ("Background IP"). Any property rights, know-how, patents and other intellectual property developed jointly during the duration of this Agreement shall be discussed and agreed upon on a case-by-case basis for joint ownership.

10.2 It is Company's responsibility to evaluate and assess any possible intellectual property and similar rights of Third Parties (including patents, patent extensions - e.g. SPCs - and any other intellectual property right) which may have the effect of preventing the import, use, possession, sale or distribution of the Substance and/or any Final Drug Product ("Third Party Rights") in the Territory and decide whether to launch or not.

10.3 Accordingly, should the Company decide to launch before the expiry of any Third Party Right in the Territory, the Company will do so at its own risk as to cost and consequences and therefore the Company shall indemnify and hold harmless Interquim and its officers, directors and employees against all costs, expenses and damages incurred by any of them as a result of any claim, demand, actions, costs liabilities, suit, injunction or judgment which are made or brought against any of them by the Third Party Right holder or its licensee because of such launch or any action in preparation of such launch or otherwise on account of consummating the transactions contemplated under this Agreement.

10.4 Interquim declares that, to the best of its knowledge, up to the Effective Date, the manufacture of the Substance does not infringe any intellectual property rights of any Third Parties in the EU, Canada, and the United States.

10.5 The Parties shall keep each other informed, on a complete and timely basis, about any claims, demands, actions and/or suits (among others, but not limited to, filling of a complaint, the receipt of a letter alleging infringement or merely offering a patent license) against them, in or out of court, alleging infringement of Third Party Rights having effects in the Territory ("IP Claims").

10.6 In the event that any Third Party makes or files an IP Claim against the Company and/or Interquim as a consequence of or derived from any activity carried out pursuant to this Agreement, the Company will take action with respect to such IP Claim, and Interquim will give to the Company all reasonable assistance required and needed by the Company, subject to any agreement to which Interquim may be a party to. The Company will promptly notify in writing to Interquim the full particulars of the IP Claim and will provide Interquim with all the relevant documentation related to such IP Claim. If the IP Claim is also received by Interquim, Interquim will immediately notify the Company and the Parties will do best efforts to agree to a common defence strategy. In the event that the Parties do not agree to a common defence strategy each Party shall perform its own defence strategy . The Company will not be entitled to settle, in or out of court, any IP Claim without having obtained the prior written approval of Interquim, whose approval will not be unreasonably withheld or delayed.

Article 11 – Audits

Upon reasonable notice, permit Arcutis, or Arcutis contracted third party, to conduct quality audits to evaluate cGMP compliance as it relates to Roflumilast. Audits shall not be more than [***] (with the exception of 'for-cause' audits) with not more than [***], unless otherwise agreed upon.

Article 12 - Term and Termination of the Agreement

12.1 This Agreement shall enter into force on the Effective Date and shall continue in effect until the expiry of the Initial Term, unless terminated earlier as specified in this Agreement. This Agreement will automatically renew for subsequent one year renewal periods, unless a prior written notice of termination is given to the other Party at least six (6) months before the end of the Initial Term or any renewal period.

12.2 Each Party shall have the right to terminate immediately this Agreement in its entirety and for all countries of the Territory by means of a written notification sent to the other Party in the event that such other Party has committed a material breach of this Agreement, if the breaching Party does not respond to the notice within sixty (60) calendar days of its receipt, or if it does respond and the non- breaching Party is not reasonably satisfied with the response or the proposed remedy, such termination shall be without prejudice to any right of indemnification which the affected Party may consider itself entitled to. Termination may be immediate, without the granting of a remedy period, in the event of a second material breach of the same obligation under this Agreement.

Parties agree that the expression material breach shall include but not be limited to (i) the breach of Confidentiality obligations,and (ii) the breach of Representations and Warranties.

12.3 In the event that subsequent to the Effective Date new information on new adverse reaction experience becomes available with respect to the Substance that makes the marketing and sale of such Substance no longer commercially viable, the Parties shall meet and determine a mutually acceptable manner in which to resolve the matter, and if no resolution can be found within three (3) months, each Party shall have the right to terminate the Agreement for the Substance immediately thereafter by giving written notice to the other Party without any liability or monetary obligations on account of such termination.

12.4 In the event that the Company decides to discontinue the formulation using the Substance, the Company shall be entitled to terminate the Agreement by means of a written notification sent to Interquim within six (6) months prior to the desired date of termination of the Agreement, provided that the Company shall be obliged to purchase (i) the total amount of Substance already manufactured by Interquim and (ii) the starting materials already purchased by Interquim that cannot be re-allocated to other Interquim's client's purchase orders. Interquim shall in good faith re-allocate the Substance to other customers. Both parties shall negotiate in good faith any other damages that may arise from this termination.

12.5 Upon expiration or termination for any reason:

(i) All rights granted pursuant to this Agreement shall automatically terminate as from the date on which termination takes effect;

(ii) The Company shall purchase from Interquim at the applicable supply price set forth in this Agreement any of the relevant Substance already ordered by the Company and manufactured but not yet delivered by Interquim on the termination date; and

(iii) The Company shall, at Interquim's option, apply for a variation of the relevant Marketing Authorization/s for any End Product in the Territory in order to exclude Interquim as authorized API manufacturer; and

(iv) Receiving Party shall return to the Disclosing Party, without retaining any copy in any format or means, the applicable Confidential Information, and refrain from using it for any purpose whatsoever, and refrain from allowing third parties to do so.

12.6 Termination or expiration of this Agreement, for whatever reason, shall be without prejudice to any rights, claims or obligations of either Party which may have accrued prior to, or become due at the date of such termination.

12.7 Neither of the Parties shall, by reason of the termination of this Agreement, be liable to the other Party for any indemnity or termination payment, compensation or benefit of any kind on account of loss of business earnings, loss of anticipated sales, loss of profits, loss of reputation or goodwill, loss of opportunity, punitive damages, indirect, special or consequential damages, except in the event of gross negligence or wilful misconduct (*dolo*).

The provisions of Articles 6, 7.3, 8,9, 10, and 14.7 will survive the termination of this Agreement.

Article 13 - Force Majeure

Neither Party to this Agreement will be liable to the other Party because of any delay or failure to perform its obligations hereunder, if and to the extent that such failure is due to a situation caused by an event beyond such Party's control and which, by the exercise of reasonable diligence and care, such Party could not reasonably have been expected to avoid, including, but not limited to, strikes, riots, wars, fire, acts in compliance with any applicable mandatory law, regulation or governmental order, any state thereof or any other domestic or foreign governmental body or instrument thereof having jurisdiction in the matter; provided however, (i) that such Party shall notify the other Party as promptly as reasonably possible should it become aware of such a situation, and (ii) that the other Party shall be entitled to terminate this Agreement if such force majeure event persists for more than ninety (90) days, without any liability or monetary obligations on account of such termination.

Article 14 – Generalities

14.1 If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, the other provisions of this Agreement shall remain in full force and effect. Such invalid, illegal or unenforceable provision shall be substituted by such a valid clause which achieves, as nearly as possible, the original intention of both Parties.

14.2 Rights and obligations under this Agreement are intuito personae, therefore this Agreement may not be transferred or assigned, in whole or in part, by either Party without prior written permission of the other Party. Notwithstanding, either Party may assign or transfer this Agreement, in whole or in part, to any of its current Affiliates notifying such fact to the other Party in writing, as stated in Article 14.8.

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

14.3 Company may assign this Agreement, upon written notice to Interquim, to any entity acquiring all or substantially all of its business to which this Agreement relates.

The entity resulting of Company's change of control by such an acquisition shall assume the totality of rights and obligations derived from the present Agreement.

14.4 The relationship of the Parties under this Agreement is that of supplier and customer and each of them is an independent contractor. Accordingly, neither the making of this Agreement nor the performance of any of the provisions herein shall be construed to make either Party an agent, trustee, employee or legal representative of the other whether expressed or implied, nor shall this Agreement be construed as a joint venture, pooling, franchise, partnership or agency. Neither Party has any authority whatsoever to act as an agent or representative of the other in any manner, nor has either Party any authority or power to act, contract for, or create or assume any obligation or liability in the other's name or on behalf of the other or otherwise bind the other in any way for any purpose, nor shall either Party hereto represent to any third parties that it possesses any such authority to bind the other Party.

14.5 This Agreement, including its Annexes contain the entire agreement between the Parties regarding the subject matter hereof and supersede any and all prior understandings whether oral or in writing. Modifications to this Agreement will only be binding if made in writing and signed by duly authorized representatives of each Party.

14.6 None of the terms of this Agreement (including its Annexes) shall be deemed to be waived except by a written document drawn expressly for such purpose and executed by the Party against whom enforcement of such waiver is sought. Failure or delay of either Party hereto to enforce any of its rights under this Agreement shall not be deemed a continuing waiver by such Party of any of its rights under this Agreement.

14.7 Any dispute arising out of or in connection with this contract, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration under the London Court of International Arbitration (LCIA) Rules, which Rules are deemed to be incorporated by reference into this clause. The number of arbitrators shall be one. The seat, or legal place, of arbitration shall be London, England. The governing law of the contract shall be the substantive law of England. The language used in the arbitral proceedings shall be English.

14.8 All notices, notifications or other communication arising from, required or permitted in connection with this Agreement or the subject matter hereof of either of the Parties hereto will be made in writing and in English and will be deemed to be sufficiently served for all purposes hereof if sent by email, with a copy sent via registered post, with acknowledgement of receipt, by registered air mail or by air courier addressed to the Party to be notified at the following addresses or to such other address that may be notified by either of the Parties in the future and given as herein required:

If to the Company:
Arcutis Biotherapeutics, Inc. 3027 Townsgate Road, Suite 300 Westlake Village,
CA 91361 Attn: [***]
Email: [***]

If to Interquim:
Interquim
C/ Joan Buscallà 10,
E-08173 Sant Cugat del Vallès, Barcelona Spain
Attn: [***]
Email: [***]

14.9 Ethical Code. Company expressly acknowledges that the corporate policies of Interquim require that all business be conducted within the letter and spirit of the Law and in a manner which is consistent with good business ethics, as Interquim commits itself to such.

14.10 Anti-corruption undertaking. The Company shall comply with, and will not cause any Party and its Affiliates, associates, directors, officers, shareholders, employees, representatives, sub-licensees or agents worldwide to be in violation of any applicable anti-corruption laws, rules and regulations, including but not limited to the United States Foreign Corrupt Practices Act (the "FCPA") or the UK Bribery Act 2010. Without limiting the foregoing, the Company will not, directly or indirectly, pay any money to, or offer or give anything of value to, any Government Official, in order to obtain or retain business or to secure any commercial or financial advantage for Interquim for itself or any of its respective Affiliates. The Company undertakes not to bribe Government Officials or any private companies or individuals, “bribes” having the following definition: Offering, promising, or giving a financial or other advantage to another person where it is intended to bring about the improper performance of a relevant function or activity, or to reward such improper performance; acceptance of the advantage offered, promised or given in itself constitutes improper performance of a relevant function or activity. “Improper Performance” means a breach of expectations that a person will act in good faith, impartially, or in accordance with a position of trust. The Company must also (1) make and keep books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets of the company, and (2) devise and maintain a system of internal accounting controls. and (3) at any time Interquim so requests in writing, but no more than once a year, grant to Interquim commercially reasonable access to said books, records, systems and accounts to verify compliance. Such inspection shall be undertaken by an independent public accountant or accounting firm appointed by Interquim and about whom the Company does not express a legitimate concern. For the avoidance of doubt, this restricted annual audit shall not apply to for- cause audits, which may be conducted at any time.

14.11. Data Protection. The legal representatives of Interquim and the Company acknowledge and consent that all personal data reflected in this Agreement, as well as those generated by the execution of this Agreement, shall be included in the files owned by Interquim and the Company, respectively, in order to manage the business relationship. Such data shall be kept for as long as the contractual relationship is in force, and any remaining obligation following termination or expiry, as applicable. Any of the above representatives may exercise their rights of access, rectification, erasure, restriction of processing, portability of data, as well as to submit any queries or suggestions in respect of the processing of personal data by writing to the Data Protection Officer using any of the following means, along with a copy of their ID document or other means of identification:

(i) By email to [***]
(ii) By post addressed to Interquim or the Company, as applicable;

The legal representatives of Interquim and the Company are entitled to submit complaints with regards to Data protection to the Competent Data Protection Authority.

This Agreement may be signed by either Party by electronic means through a Qualified Trust Services Provider which authenticity can be demonstrated and in accordance with applicable legal requirements. Such electronic signatures will have the same effect and validity as the manual signature.

And in proof of their agreement, the Parties sign this Agreement, executed by their respective duly authorized legal representatives on the date above written.

ARCUTIS BIOTHERAPEUTICS, INC.
By: /s/ Frank Watanabe
Frank Watanabe
Title: President and Chief Executive Officer

Interquim, S.A.U.
By: /s/ Pedro de Antonio Ferrer
Pedro de Antonio Ferrer
Title: Legal representative

By: /s/ David Ferrer Puig
David Ferrer Puig
Title: Legal representative

ANNEX I

[***]

Annex II Specifications [***]

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., and
(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.;

of our report dated February 16, 2021, with respect to the financial statements of Arcutis Biotherapeutics, Inc. included in this Annual Report (Form 10-K) of Arcutis Biotherapeutics, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Los Angeles, California
February 16, 2021

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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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(s) 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 16, 2021

By: /s/ Todd Franklin Watanabe

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

Exhibit 31.2

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

I, John W. Smither, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 16, 2021

By: /s/ John W. Smither

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

Exhibit 32.1

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

In connection with the Annual Report of Arcutis Biotherapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and John W. Smither, Chief Financial Officer of the Company, 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 16, 2021 By: /s/ Todd Franklin Watanabe

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

Date: February 16, 2021 By: /s/ John W. Smither

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