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, 2019
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For transition period from to
Commission File Number: 001-39186

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-2974255**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
2945 Townsgate Road, Suite 110 **Westlake Village, California** **(Address of Principal Executive Offices)**	**91361** **(Zip Code)**

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

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

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

The number of shares of the registrant’s Common Stock outstanding as of March 1, 2020 was 38,088,959.

DOCUMENTS INCORPORATED BY REFERENCE:

None.

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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, ARQ-151, 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 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 ARQ-151, ARQ-154, 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;
- 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.

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 topical treatments with significant potential to address immune-mediated dermatological diseases and conditions, or immuno-dermatology. Our strategy is to identify and develop treatments against validated biological targets in dermatology that deliver a differentiated clinical profile that addresses major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product candidate, ARQ-151, is in Phase 3 clinical trials in plaque psoriasis. ARQ-151 is a topical cream formulation of roflumilast, a highly potent and selective phosphodiesterase type 4, or PDE4, inhibitor, which we are developing for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. PDE4 is an established biological target in dermatology, with multiple PDE4 inhibitors approved by the U.S. Food and Drug Administration, or FDA. We have successfully completed a Phase 2b study of ARQ-151 in plaque psoriasis, demonstrating potential symptomatic improvement and favorable tolerability of ARQ-151 in this population. We have initiated three Phase 3 studies in plaque psoriasis, with topline data expected in the first half of 2021. We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, and expect to report topline data in the first half of 2021. We also completed a Phase 2 proof of concept study of ARQ-151 in atopic dermatitis and plan to initiate a Phase 2b study in the second half of 2020, with topline results expected in the second half of 2021.

In addition, we are developing ARQ-154, a topical foam formulation of ARQ-151, and have initiated a Phase 2 proof of concept study in seborrheic dermatitis and a Phase 2b study in scalp psoriasis. We expect to report topline data in the second half of 2020 with respect to seborrheic dermatitis and in Q4 2020/Q1 2021 with respect to scalp psoriasis. Beyond this, in 2020 we also plan to initiate clinical studies of ARQ-252, a potent and highly selective topical janus kinase type 1, or JAK1, inhibitor for the treatment of hand eczema and vitiligo. 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.

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 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 and atopic 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, which can lead to disease flares. In psoriasis, vitamin D analogues have demonstrated 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, have lower response rates than TCS and are associated with application site burning. TCIs also have a boxed warning for cancer risk.

Biologic and systemic therapies are also available, 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 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.

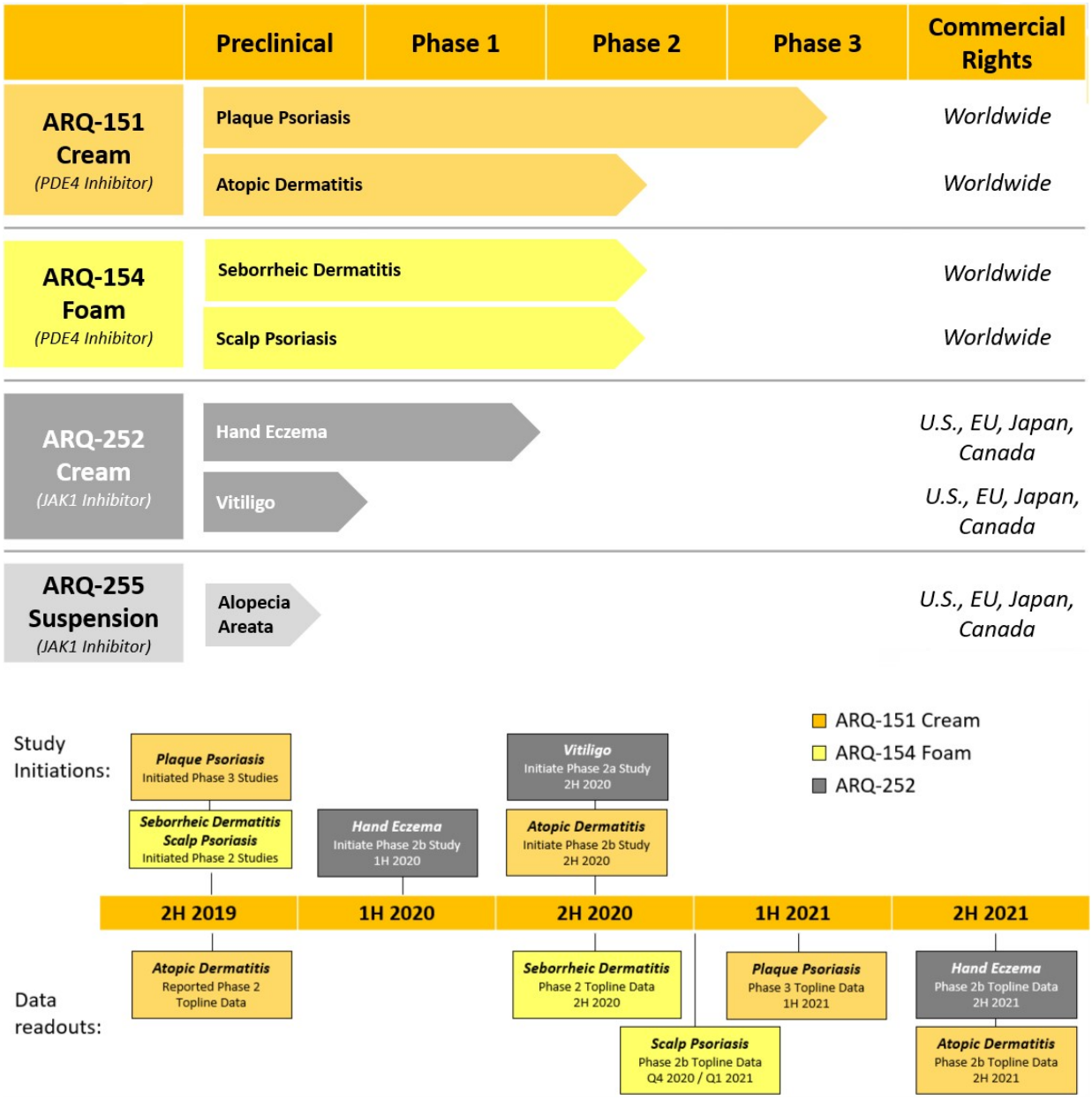
Given the limitations associated with TCS, other topical therapies, biologics, and systemic therapies, we believe patients with inflammatory skin conditions are dissatisfied with their current treatment options. We believe that there is a significant opportunity to leverage developments in other fields 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.

We are developing ARQ-151 for the treatment of plaque psoriasis and atopic dermatitis. High-potency steroids are the current standard of care for plaque psoriasis, and low- to mid-potency steroids are the current standard of care for atopic dermatitis, but steroids are associated with suppression of the hypothalamic-pituitary-adrenal axis, or HPA axis (one of the body's four neuroendocrine systems, playing a central role in regulating portions of the metabolic, cardiovascular, immune, reproductive and central nervous systems), skin atrophy (thinning), striae (stretch marks), and telangiectasias (spider veins), among other side effects. Furthermore, some of these side effects (e.g., striae) are irreversible, persisting even after therapy is discontinued. Based on market research and our internal estimates, we estimate the population of patients treated with prescribed topical therapies in the United States is approximately 2.5 million patients and 5.4 million patients for psoriasis and atopic dermatitis, respectively. We estimate our addressable market opportunity, which focuses on patients treated by dermatologists with topical therapies, for each of psoriasis and atopic dermatitis is 2.0 million patients and 1.0 million patients, respectively.

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. We do, however, believe that there will be an impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials.

Our Pipeline

The following charts summarize our product pipeline, including our lead product candidate, ARQ-151, 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 that address significant unmet needs in immuno-dermatology. Key elements of our strategy include:

- ***Rapidly develop and commercialize our lead product candidate ARQ-151 for the treatment of patients with plaque psoriasis and atopic dermatitis.*** We plan to develop ARQ-151 for the treatment of plaque psoriasis and atopic dermatitis. Based on the clinical data generated to date, we believe ARQ-151 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 initiated three Phase 3 clinical trials and a long-term safety study of ARQ-151 with topline results for all four studies expected in the first half of 2021. In atopic dermatitis, we have completed a Phase 2 proof of concept study of ARQ-151 and plan to initiate a Phase 2b study in the second half of 2020, with topline results expected in the second half of 2021.
- ***Expand our addressable market with ARQ-154.*** ARQ-154 is a foam formulation of ARQ-151 for the treatment of scalp psoriasis and seborrheic dermatitis that we developed to treat hair-bearing areas of the body like the scalp where a cream is not suitable. Based on the results of our Phase 2 studies with ARQ-151, we believe ARQ-154 has the potential to offer patients symptomatic improvement similar to high-potency steroids in scalp psoriasis and may be superior to standard of care treatments for seborrheic dermatitis, while potentially maintaining a low risk of side effects and favorable tolerability. We have initiated a Phase 2 proof of concept study in seborrheic dermatitis and a Phase 2b study in scalp psoriasis.
- ***Continue to innovate and develop our product pipeline of therapeutics which we believe have the potential to be best-in-class in immuno-dermatology.*** We plan to develop ARQ-252, a JAK1 inhibitor with a high relative selectivity to JAK1 over JAK2, for the treatment of hand eczema and potentially vitiligo and 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 plan to initiate our Phase 2b study in hand eczema in the first half of 2020 and our Phase 2a study in vitiligo in the second half of 2020. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.
- ***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.
- ***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.

ARQ-151

Overview

Our lead product candidate, ARQ-151, is a topical cream containing roflumilast, a PDE4 inhibitor, that potentially offers symptomatic improvement similar to a high-potency steroid, a favorable tolerability profile, the ability to treat chronically, and little to none of the application site reactions associated with many existing treatments. We are currently developing ARQ-151 for plaque psoriasis, including intertriginous psoriasis, as well as atopic dermatitis. We have successfully completed a Phase 2b study of ARQ-151 in plaque psoriasis. We have initiated three Phase 3 clinical trials in plaque psoriasis and have also completed enrollment in a long-term safety study, and expect to report topline data for all four studies in the first half of 2021. We also completed a Phase 2 proof of concept study of ARQ-151 in atopic dermatitis and plan to initiate a Phase 2b study in the second half of 2020, with topline results expected in the second half of 2021.

In July 2018, we executed a licensing agreement with AstraZeneca AB for exclusive worldwide rights to roflumilast, the PDE4 inhibitor used as the active pharmaceutical ingredient in ARQ-151 and ARQ-154, 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 and pharmacokinetic patents/applications in the United States and other jurisdictions from four distinct patent families, which should provide us with exclusivity for the formulation that is intended to be marketed at least through 2037. We estimate there are a total of 8.6 million patients suffering from psoriasis and 19.2 million patients suffering from atopic dermatitis in the United States. Based on market research and our internal estimates, we estimate the population of patients treated with prescribed topical therapies in the United States is approximately 2.5 million patients and 5.4 million patients for psoriasis and atopic dermatitis, respectively. We estimate our primary addressable market opportunity, which focuses on patients treated by dermatologists with topical therapies, for each of psoriasis and atopic dermatitis is 2.0 million patients and 1.0 million patients, respectively.

Mechanism of Action

PDE4 is an intracellular enzyme that regulates the production of pro-inflammatory and anti-inflammatory cytokines and cell proliferation via the degradation of cyclic AMP, or cAMP. PDE4 inhibition can inhibit inflammatory responses through, among other pathways, reductions in TNF-$\propto$, interferon-*y*, interleukin-4 (IL-4), interleukin-13 (IL-13), interleukin-17 (IL-17) and interleukin-23 (IL-23). Moreover, PDE4 inhibition can also promote the barrier function of keratinocytes via suppression of inflammatory mediator production. PDE4 has been implicated in a wide range of inflammatory diseases including asthma, COPD, psoriasis, atopic dermatitis, inflammatory bowel diseases, rheumatoid arthritis and lupus.

Product Profile & Differentiation

ARQ-151 is a topical cream formulation of roflumilast, a highly potent and selective PDE4 inhibitor that was approved by the FDA for systemic treatment to reduce of the risk of exacerbations of COPD in 2011. ARQ-151 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, and does not stain clothing or bedding or have an unpleasant smell.

The table below shows the relative potency of roflumilast compared to the active ingredients in two FDA-approved PDE4 inhibitors, demonstrating a potency advantage of roflumilast of approximately 25x to in excess of 300x.

PDE4 Inhibitor Potency

A lower IC50 value (the concentration at which a biologic target's activity is inhibited by 50% and a non-clinical measure of a drug's potency), indicates a higher affinity of binding to the various PDE4 isoforms and thus greater potency.

IC50 (nM)	PDE4B	PDE4A1A	PDE4B1	PDE4C1	PDE4D7
Roflumilast	0.47	0.33	0.28	0.95	0.53
Crisaborole (Eucrisa)	75	55	61	340	170
Apremilast (Otezla)	39	9	16	48	12

We believe ARQ-151 addresses major unmet needs in the treatment of plaque psoriasis and atopic dermatitis and, based on the clinical data generated to date, has the potential to offer symptomatic improvement similar to high-potency steroids, a low risk of side effects, a favorable tolerability profile to enable chronic administration in all anatomical areas, and a convenient and patient-friendly topical formulation.

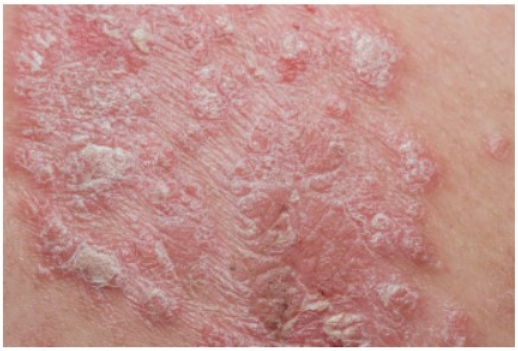
Plaque Psoriasis

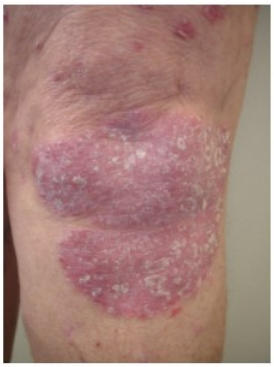
Psoriasis Background

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, which presents a challenge for drug delivery, as the creams and ointments typically used to treat psoriasis on other body areas are not appropriate for use on the scalp. About 15% of plaque psoriasis patients have plaques in their intertriginous regions, which are particularly difficult to treat because these areas tend to have thinner, more easily irritated skin, and are more prone to steroid-related side effects, especially skin atrophy (thinning), striae (stretch marks) or telangiectasia (spider veins). Approximately 10% of plaque psoriasis patients have plaques on their face, which similarly has thinner, more easily irritated skin and greater vulnerability to side effects. Treatment of facial plaques is also complicated by proximity to the eyes, and the consequent heightened safety concerns, specifically increased risk for development of cataracts and glaucoma due to steroid exposure. One in three plaque psoriasis patients has plaques on their elbows and knees, which are frequently treatment resistant. Even with biologic therapies, plaques on the elbows and knees are often the last areas to resolve.

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.





Figures: Plaque Psoriasis

Source: DermNet (right)

Pruritus or itching is a particularly common and bothersome symptom for patients. A recent chart review of U.S. psoriasis patients by Adelphi Group found nearly half of moderate to severe patients and one in five mild patients reported experiencing significant itching (as indicated by reports of at least a 4 on a 10-point scale) sometimes, usually or all of the time. Three quarters of moderate to severe patients with itch, and one third of mild patients with itch reported that the itching also disturbed their ability to sleep.

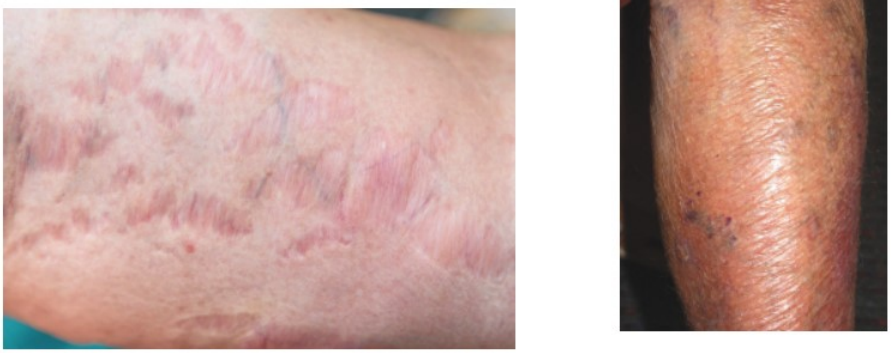
In addition to the direct clinical challenges of psoriasis, it has been documented that patients with plaque psoriasis suffer substantial psychosocial impacts from their disease, including: social stigmatization, feelings of rejection and shame, guilt, impaired sexual intimacy, discrimination in the workplace, difficulty finding employment or working outside the home, financial hardships, increased work absenteeism and reduced productivity. Patients with psoriasis also have a 50% greater chance of depression than the general population.

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. The Adelphi Group U.S. chart review discussed above found that 95% of all patients reviewed had received a topical treatment at some point in their therapy, 86% had received a topical as the first line therapy, and 71% continued to receive topical therapy, either alone or in combination with other treatments. Despite their widespread use, existing topical therapies all possess substantial shortcomings:

- ***Topical steroids***, especially the high-potency topical steroids generally used to treat psoriasis, are associated with HPA axis suppression, skin atrophy (thinning), striae (stretch marks), and telangiectasia (spider veins), among other side effects. Furthermore, some of these side effects are irreversible,

persisting even after therapy is discontinued. 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. For example, the label for clobetasol propionate, the most commonly used high-potency steroid, limits use to two consecutive weeks and use on the face or intertriginous regions is contraindicated.



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

- ***Vitamin D3 analogs*** such as calcipotriene, 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. For example, Taclonex ointment is limited to 4 weeks of treatment.

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 on them. But due to the limitations on duration of treatment to between two and eight weeks, physicians are quickly confronted with a conundrum of how to manage their psoriasis patients chronically. Most will switch the patient to a low- to mid-potency steroid or to a vitamin D analog. These “step down” options provide less symptomatic improvement, and in the case of vitamin D, are often irritating. Also, rebound is a known challenge with steroids, where after steroid discontinuation, the psoriasis returns even worse than it was before steroid treatment was initiated. Thus, patients are constantly cycling between short courses of high-potency steroids and “step down” maintenance treatments.

While biologic therapies, including drugs such as Enbrel, Cosentyx, Humira, and Stelara, are available for treatment, their use 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, which can be as much as $60,000 per year, consequent reimbursement and access restrictions, frequent high patient co-pays, perceived risk of side effects, and patient fear of injection.

Non-biologic systemic therapy options for psoriasis exist, but their use is also limited, according to Decision Resources Group, representing approximately 8% of patients worldwide, and 13% of patients in the United States. Methotrexate remains the most widely used systemic therapy, although its use continues to decline due to concerns about side effects and mandatory routine monitoring. Apremilast (Otezla), an oral PDE4 inhibitor, is another systemic option, but although it generated approximately $2 billion in global sales in all indications in 2019, it has less than 2% U.S. patient share in psoriasis due to limitations on its use to moderate-to-severe patients, modest symptomatic improvement, and frequent adverse events, or AEs.

Due to the shortcomings of existing topical therapies and the lack of options providing robust symptomatic improvement with chronic treatment, as well as the inherent challenges of treating psoriasis, the majority of patients

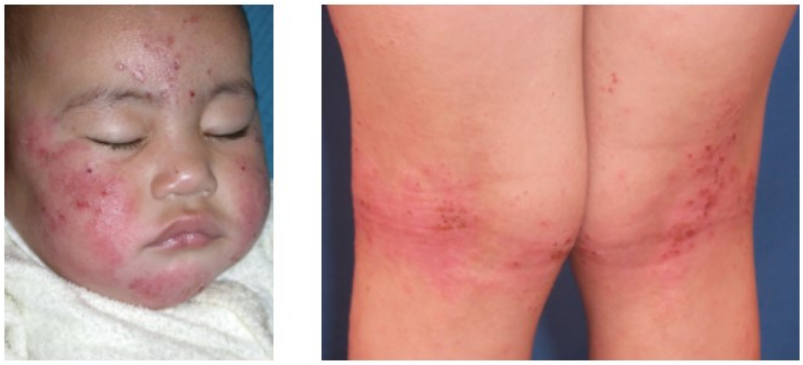
continue to suffer from symptoms even when on treatment. Therefore, there remains a need for a non-steroidal topical treatment that is as effective as high-potency steroids, that can be used chronically, has a low risk of side effects and is well tolerated, and that can be used on all anatomical areas.

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), in some cases half of the body or more. 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 most of the patients are pediatric, safety and tolerability of atopic dermatitis treatments is paramount and explains the predominance of topical treatments. Atopic dermatitis imposes a substantial burden on both the patient and, particularly in the case of pediatric patients, the 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. Parents and families of pediatric patients with atopic dermatitis can also be impacted by a lack of sleep, emotional distress due to their child’s suffering, and added workload caring for the atopic dermatitis patient. 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 topical calcineurin inhibitors, or TCIs, and these two classes of drugs constituted 50% of atopic dermatitis prescription sales in 2017. While topical steroids are commonly used in atopic dermatitis, they are infrequently prescribed in patients with atopic dermatitis on the face or diaper/groin area. In lieu of steroids, or in response to parental concerns about steroid use, physicians frequently prescribe TCIs in patients with atopic dermatitis, especially for patients with lesions on the face or diaper/groin area. Biologic use for atopic dermatitis is currently limited. Dupixent, approved in early 2017, is the first biologic for atopic dermatitis for the treatment of adults and adolescents ages 12 and above with moderate-to-severe atopic dermatitis. Dupixent generated $2.3 billion in global net sales in 2019 across all indications. Despite these impressive sales results, Dupixent was used in less than 1% of atopic dermatitis patients.

Despite their widespread use, existing topical therapies for atopic dermatitis 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. Consequently, 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, which can be an obstacle to treatment for physicians.
- ***Topical calcineurin inhibitors*** are generally seen as providing less symptomatic improvement than topical steroids and are also associated with some application site burning. Probably most significant, 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. While some experts have expressed skepticism over the warning, TCI sales dropped 30% the year after the boxed warning and have not recovered since.
- ***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 disadvantaged reimbursement status compared to other atopic dermatitis treatments.

Physicians are dissatisfied with current treatments due to overall suboptimal symptomatic improvement, ability to control itching, and impact on patient/parent quality of life. Patients with, or parents of patients with, atopic dermatitis are dissatisfied with overall suboptimal symptomatic improvement, sustained symptomatic improvement over time, and the inconvenience of many of the topical treatments, including the greasy residue, the amount of time required to apply, and the general messiness of treatments.

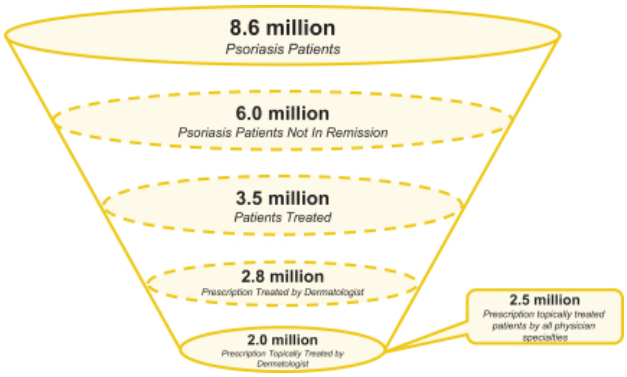
Therefore, there remains a need for a non-steroidal topical treatment that provides more symptomatic improvement than current topical treatments, has a low risk of side effects, is well tolerated, and can be used chronically in pediatric patients and on all areas of the body.

Our Market Opportunity

Plaque Psoriasis

The sales of prescription treatments for psoriasis are large and growing rapidly. According to Decision Resources Group, the worldwide market for psoriasis will grow from $14.5 billion in 2018 (of which $12.2 billion was in the United States) to $22.7 billion in 2027, representing a 5% CAGR. The vast majority of prescription psoriasis sales are for biologic therapies, including drugs such as Enbrel, Cosentyx, Humira, and Stelara, which in 2018 represented $12.1 billion (83%) of all worldwide sales and 85% of U.S. sales.

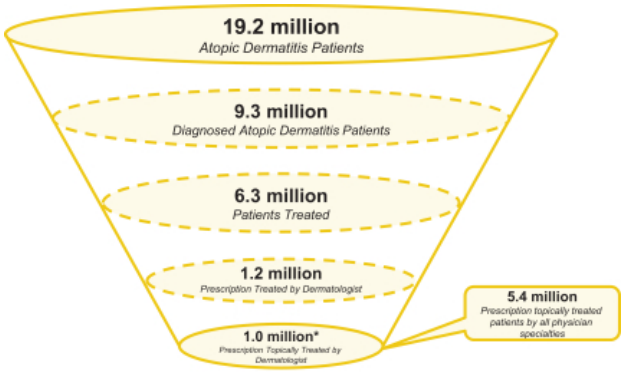
We believe there is a significant market opportunity for us to capture within plaque psoriasis. As depicted below, we estimate there are approximately 8.6 million psoriasis patients in the United States, of which approximately 6.0 million patients are not in remission and 3.5 million are seeking some form of treatment for the disease, of which approximately 82% are treated by dermatologists. We estimate that in the United States, 2.5 million patients are treated with prescription topical therapies, of which 2.0 million patients are treated with topical prescriptions by a dermatologist.



Atopic Dermatitis

While the current sales of prescription treatments for atopic dermatitis are considerably smaller than that for psoriasis, they are similarly expected to grow rapidly with the emergence of newer and better therapies. According to Decision Resources Group, the worldwide market in 2018 was $3.2 billion, but is expected to grow to $24 billion by 2028, representing a 22% CAGR.

We believe there is a significant market opportunity for us to capture within atopic dermatitis. As depicted below, we estimate there are approximately 19.2 million atopic dermatitis patients in the United States, of which 9.3 million patients are diagnosed with atopic dermatitis. We estimate approximately 6.3 million atopic dermatitis patients are treated, of which 1.2 million patients are treated by dermatologists. We estimate that in the United States, 5.4 million patients are treated with prescription topical therapies, of which 1.0 million are treated with topical prescriptions by a dermatologist.



* Based on the percentage of pediatric patients with atopic dermatitis treated with topical prescriptions from dermatologists. A majority of patients suffering from atopic dermatitis are pediatric patients.

We believe ARQ-151 and ARQ-154 have the potential to address the limitations of current treatments for plaque psoriasis and atopic dermatitis.

ARQ-151 Clinical Development

Indication	Study Name	Phase	Number of Patients	Status
	151-101	Phase 1/2a	89	Completed
	151-201	Phase 2b	331	Completed
Plaque	151-202	Phase 2b	333	Ongoing
Psoriasis	151-301	Phase 3	~ 400 (Expected)	Ongoing
	151-302	Phase 3	~ 400 (Expected)	Ongoing
	151-306	Phase 3	~ 250 (Expected)	Ongoing
	151-107	Phase 1	16	Ongoing
Atopic	151-102	Phase 1	16	Completed
Dermatitis	151-212	Phase 2 proof of concept	136	Completed
	151-105	Phase 1	~ 22 (Expected)	Ongoing

We have completed two Phase 2 clinical trials evaluating ARQ-151 in adults with plaque psoriasis, one Phase 2 clinical trial evaluating ARQ-151 in adolescents and adults with atopic dermatitis, and one Phase 1 clinical trial evaluating the pharmacokinetics of ARQ-151 in adults with atopic dermatitis. One Phase 2 clinical trial and three Phase 3 clinical trials are currently ongoing in plaque psoriasis. We plan to initiate a Phase 2b atopic dermatitis study in the second half of 2020.

Plaque Psoriasis

Completed Trials

ARQ-151-201 (Phase 2b Study)

The most recent study completed with ARQ-151 in plaque psoriasis 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) ARQ-151 0.3% topical cream, (2) ARQ-151 0.15% topical cream, 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 ARQ-151 0.3% arm, 92.0% in the ARQ-151 0.15% arm, and 78.9% in the vehicle arm.

Primary Endpoint

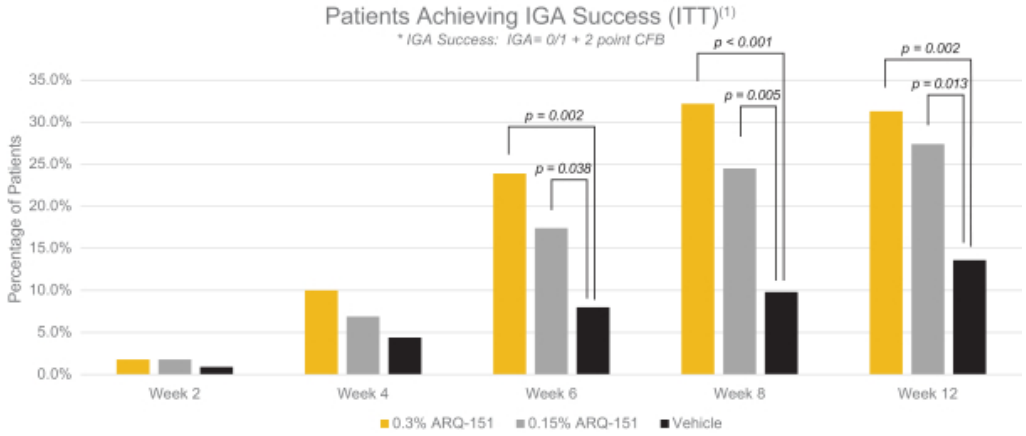
The primary efficacy endpoint of our Phase 2b study was the percentage of subjects attaining a score of “clear” or “almost clear” on the IGA scale at week 6.

Both ARQ-151 0.3% and ARQ-151 0.15% separated from vehicle with statistical significance on the primary endpoint of percentage of patients achieving an IGA of “clear” or “almost clear” at week 6, with 28.0% of patients treated with ARQ-151 0.3% and 22.8% of patients treated with ARQ-151 0.15% achieving “clear” or “almost clear”, compared to 8.3% treated with vehicle (ARQ-151 0.3%: $p < 0.001$; ARQ-151 0.15%: $p = 0.004$).

Key Secondary Endpoint

The likely registrational endpoint for any topical psoriasis product is “IGA Success”, which is the percentage of patients attaining an IGA score of “clear” or “almost clear” PLUS a 2-grade improvement from baseline on the 5-

point IGA scale. The results for this endpoint from the Phase 2b plaque psoriasis study are shown in the graph below:



(1) The intention to treat, or ITT, population includes all randomized patients. This clinical trial study population is intended to represent suitable patients and to be reflective of what might be seen if the treatment was used in clinical practice.

As shown in the graph above, both ARQ-151 0.3% and ARQ-151 0.15% separated from vehicle and demonstrated statistical significance on the percentage of patients achieving IGA Success at 8 weeks, with 32.2% of patients treated with ARQ-151 0.3% and 24.5% of patients treated with ARQ-151 0.15% achieving IGA Success, compared to 9.8% treated with vehicle.

Additional Secondary Endpoints

Additional secondary endpoints for our Phase 2b study included:

- The percentage of patients attaining a 75% or 90% reduction from baseline on their PASI score (PASI-75 and PASI-90) at weeks 4, 6, 8 and 12 compared to baseline;
- Among subjects with plaques in their intertriginous regions, an I-IGA of “clear” or “almost clear” PLUS a 2-grade improvement from baseline at weeks 4, 6, 8 and 12.
- Among subjects with documented pruritus (itching) with a baseline WI-NRS pruritus score of $\geq$ 6, at least a 4-point reduction from baseline at weeks 4, 6, 8 and 12.
- The mean change from baseline on a Patient Reported Outcomes, or PRO, assessment called the Psoriasis Symptom Diary, or PSD, at weeks 4, 6, 8 and 12.

The figure below includes photographs that are representative of patients of our Phase 2b study:

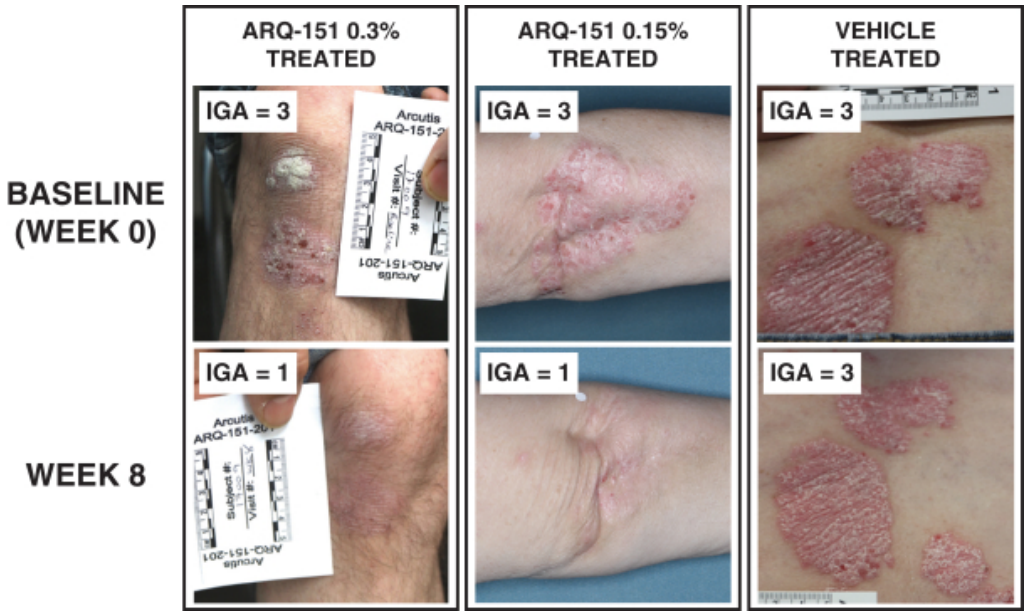


Figure: Representative Subject Photographs from Study ARQ-151-201

The upper row of photographs shows psoriatic plaques of individual study subjects in the ARQ-151 0.3% (left), ARQ-151 0.15% (middle) and vehicle (right) groups at baseline (Week 0). All 3 subjects were graded “moderate” (IGA 3) at baseline, as were 77.3% of all subjects enrolled in the study. The lower row of photographs shows those exact same psoriatic plaques of the exact same individual subjects after 8 weeks of treatment. The vehicle patient remained “moderate” (IGA 3). The subjects on both ARQ-151 0.15% and ARQ-151 0.3% achieved IGA Success – both subjects were IGA 1 at Week 8, improving 2 points from baseline. These two subjects are representative of the patients achieving IGA Success in the study.

In published data from third party clinical trials involving halobetasol and bethamethasone dipropionate (Class 1 ultra high- and high-potency steroids), halobetasol and betamethasone dipropionate demonstrated a mean IGA Success rate of 32.5% at 8 weeks. Based on a retrospective post-hoc cross-trial comparison that we compiled based on published data and our Phase 2b study, we believe that ARQ-151 is likely to demonstrate similar mean IGA Success to these Class 1 steroids. In data from our Phase 2b study of ARQ-151, ARQ-151 0.3% demonstrated an IGA Success rate of 32.2% at 8 weeks. The results of this retrospective post-hoc cross-trial comparison may not be directly comparable, as they are not from a single head-to-head clinical trial. Further, while we believe this data is useful in informing the design of future clinical trials and potential for ARQ-151, cross-trial comparisons involve the inherent bias of post-hoc manipulation of data and choice of analytical methods, as well as methodological issues surrounding heterogeneity among studies contributing to the analyses; therefore, it is important to view such results in light of the totality of all available information, such as individual study results on pre-specified analyses of endpoints. This cross-study comparison will not be used to support regulatory filings for ARQ-151.

The chart below shows a comparison of data across these separate clinical trials.

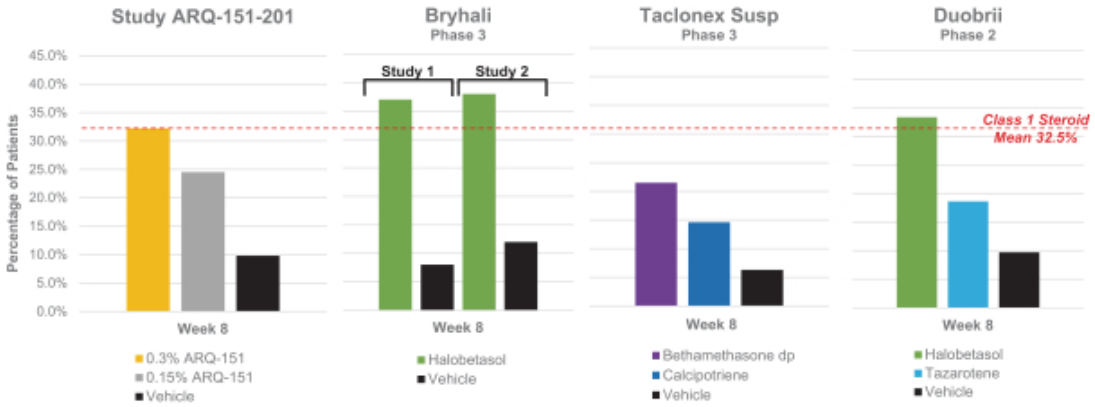


Figure: Comparison of IGA Success Rates Across Topical Psoriasis Trials

In our Phase 2b study, ARQ-151 0.3% also demonstrated promising results based on percentage of patients achieving PASI-75 (31.3% in patients with moderate-to-severe psoriasis for ARQ-151 0.3% at week 8). Additionally, patients did not experience the frequent gastrointestinal side effects reported with certain other treatments. For example, ARQ-151 0.3% reported rates of diarrhea and nausea of 0.9% and 0.9%, respectively, in our Phase 2b study.

In Phase 3 studies, oral apremilast (Otezla) achieved response rates of 28.8% and 33.1% in their Phase 3 studies at 30 mg BID (twice a day) at week 16, compared to placebo response rates of 5.3% and 5.8%, in each trial, respectively. In Phase 3 studies, Otezla reported diarrhea and nausea rates of 18.8% and 15.7%, respectively.

Both ARQ-151 0.3% and ARQ-151 0.15% demonstrated rapid onset of effect, with both doses statistically separating from vehicle as early as week 2 on mean percent CFB in PASI. The chart below shows mean percent CFB in PASI over the course of the study.

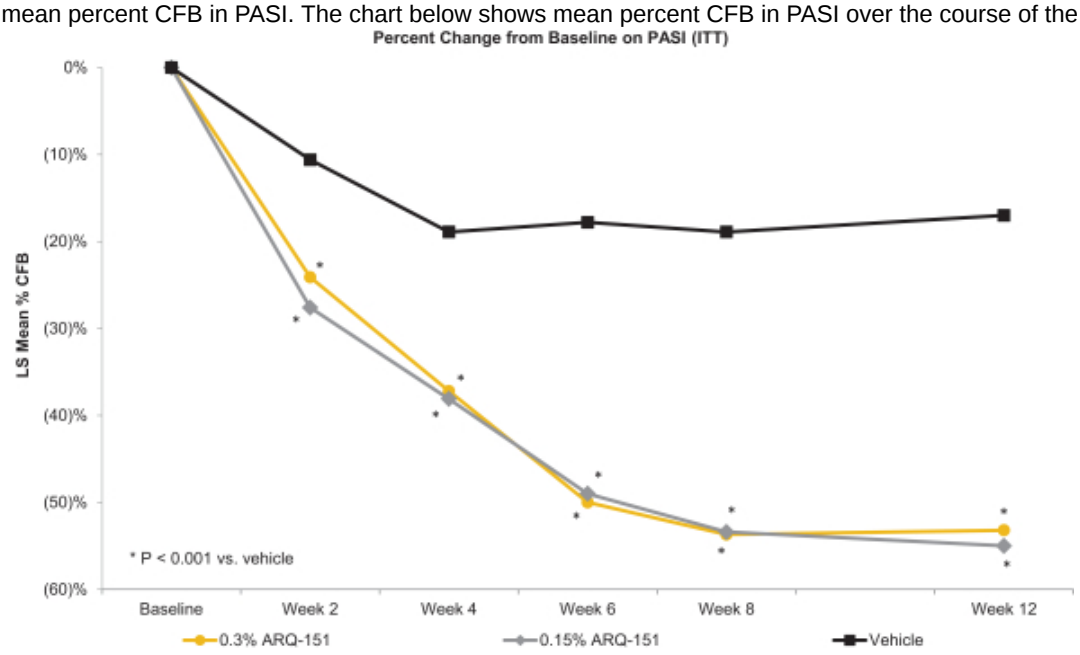


Figure: Percent Change from Baseline on PASI in Study ARQ-151-201

Additionally, statistically significantly more patients treated with ARQ-151 0.3% achieved a 75% improvement in PASI score (PASI-75) at 8 weeks than patients treated with vehicle (31.3% on ARQ-151 0.3%

versus 13.2% on vehicle, p = 0.002), and more patients treated with ARQ-151 0.3% achieved a 90% improvement in PASI score (PASI-90) at 8 weeks than patients treated with vehicle (16.9% on ARQ-151 0.3% versus 6.0% on vehicle, p = 0.015).

As noted earlier, psoriatic plaques in the intertriginous regions are particularly challenging to treat. In this study, ARQ-151 demonstrated very strong results in the treatment of intertriginous plaques. In fact, 88.5% of patients treated with ARQ-151 0.3% who had intertriginous plaques at baseline achieved an I-IGA of “clear” (I-IGA = 0) by week 8, and 44.6% of patients treated with ARQ-151 0.15% who had intertriginous plaques at baseline achieved an I-IGA of “clear” (I-IGA = 0) by week 8 compared to 30.6% of vehicle patients achieving an I-IGA of “clear” (I-IGA = 0) by week 8 (p = 0.003).

Plaque psoriasis patients suffer from a number of symptoms associated with their disease, including itching, burning, stinging, skin cracking, and pain, in addition to the thickened, red and scaly plaques that are the hallmark of the disease. In Study ARQ-151-201, patients were asked to evaluate these symptoms using the PSD, a validated psoriasis PRO. Both doses of ARQ-151 demonstrated statistically significant (ARQ-151 0.3%: p<0.001; ARQ-151 0.15%: p<0.001) reductions in the total PSD score compared to vehicle at week 8, with statistical separation at week 2 (ARQ-151 0.15%) or week 4 (ARQ-151 0.3%). ARQ-151 0.3% also statistically separated from vehicle in reductions of itch as measured by WI-NRS, with 32.9% of patients with significant itching (baseline WI-NRS $\geq$ 6) treated with ARQ-151 0.3% experiencing at least a 40% reduction in their WI-NRS score at week 2 (p = 0.034), compared to 28.4% of patients treated with ARQ-151 0.15% and 16.7% of patients treated with vehicle. At week 8, 64.6% of patients with significant itching (baseline WI-NRS > 6) treated with ARQ-151 0.3% experienced at least a 40% reduction in their WI-NRS score at week 8, compared to 58.2% of patients treated with ARQ-151 0.15% and 42.3% treated with vehicle.

Safety

In Study ARQ-151-201, ARQ-151 was well-tolerated by the subject population. The table below summarizes TEAEs in the study.

Table: Treatment-Emergent Adverse Events in ARQ-151-201

	ARQ-151 Cr 0.3% (N=109)	**ARQ-151 Cr 0.15% (N=110)**	**Vehicle (N=107)**
Subjects with any TEAE	42 (38.5%)	30 (27.3%)	32 (29.9%)
Number of TEAEs	85	51	47
Subjects with any Tx-Related TEAE	6/7/2004	2/3/2007	6/7/2005
Number of Related TEAEs	15	3	8
Subjects with any SAE	1 (0.9%)(a)	1 (0.9%)(b)	2 (1.9%)(c)
Number of SAEs	1	1	2
Subjects who discontinued Study Drug due to AE	1 (0.9%)	0	2/3/2008
Subjects who discontinued Study due to AE	1 (0.9%)(d)	0	2 (1.9%)(e)

(a) *One subject in the ARQ-151 0.3% group experienced worsening of chest pain. The subject had a history of cardiovascular disease, and the investigator deemed the AE not to be treatment related.*

(b) *One subject in the ARQ-151 0.15% group developed a 1.4 millimeter deep non-ulcerated Melanoma. The melanoma was not an area of treatment, and the investigator deemed the AE not to be treatment related.*

(c) *One subject in the Vehicle group experienced an Acute Infarction of the Left Basal Ganglia deemed not to be treatment related by the investigator; another subject in the Vehicle group experienced a Spontaneous Miscarriage, deemed to be possibly treatment related by the investigator.*

(d) *One subject in the ARQ-151 0.3% group discontinued from the study on day 18 due to an adverse event of “psoriasis”.*

(e) *Two subjects in the Vehicle group discontinued from the study due to AEs: one subject had an adverse event of “mood swings”, the other subject had an adverse event of “contact dermatitis”.*

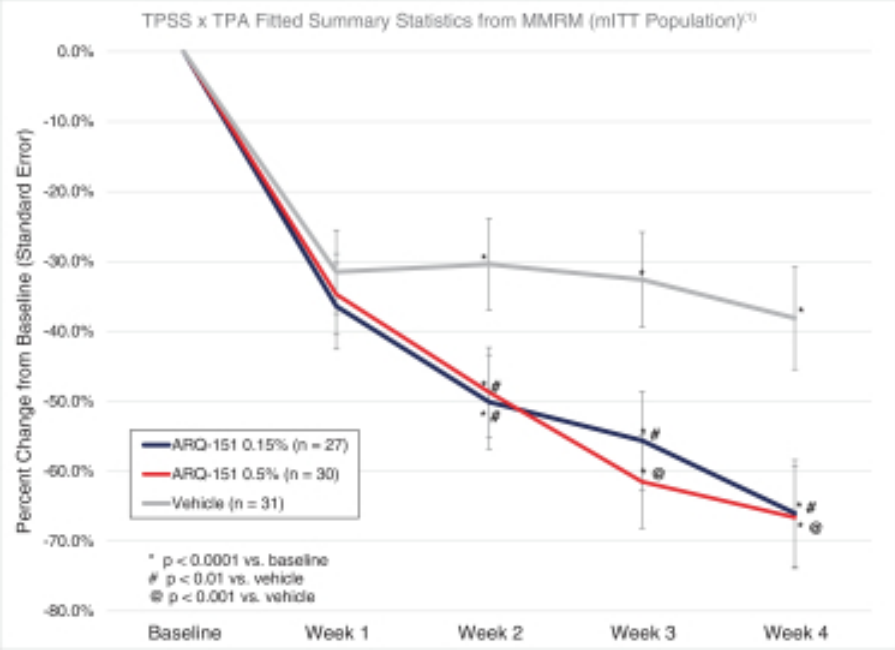
The incidence of AEs of special interest, such as the application site adverse reactions that are commonly associated with many other topical psoriasis treatments or the gastrointestinal side effects commonly seen with oral administration of roflumilast or other oral PDE4 inhibitors, was also low throughout this study:

- There was no evidence of burning or stinging at the site of application, as judged by either study subjects or investigators.
- Rates of gastrointestinal AEs were low and balanced across groups (ARQ-151 0.3% = 3.6%; ARQ-151 0.15% = 1.8%; Vehicle = 1.9%); none of those occurring in active-treated subjects led to study discontinuation, and only one subject experienced an AE (frequent bowel movements) which was deemed by the investigator to be likely, possibly, or probably related to treatment.
- Rates of psychiatric AEs were also low and balanced across groups (ARQ-151 0.3% = 2.8%; ARQ-151 0.15% = 1.8%; Vehicle = 2.8%), and none of those that occurred in active-treated subjects led to study discontinuation.
- Weight change during the study was uncommon, with weight loss of > 5% balanced across treatment groups, comparable rates of weight loss > 5% and weight gain > 5%, and no instances of weight loss > 10%.

ARQ-151-101 (Phase 1/2a Study)

We earlier conducted a multi-center, multi-national, double-blind, vehicle-controlled Phase 1/2a study of ARQ-151, in which 89 adults with plaque psoriasis were randomized to receive 4 weeks of: (1) 0.5% ARQ-151 topical cream, (2) 0.15% ARQ-151 topical cream, or (3) matching vehicle. Patients applied test article once daily to between one and three “target plaques” totaling no more than 5% BSA. The primary efficacy endpoint was the change from baseline in the product of the Target Plaque Severity Score (TPSS), measuring redness, thickness, and scaling of a target plaque, and the Target Plaque Area (TPA) of the target plaque(s). The results for this endpoint are shown in the following chart:

TPSS x TPA Fitted Summary Statistics from MMRM (mITT Population) (1)



(1) Product of Target Plaque Severity Score, or TPSS, and Target Plaque Area, or TPA, fitted summary statistics from Mixed effect Model Repeat Measurement (modified ITT population).

Figure: Improvement in Plaque Psoriasis by ARQ-151 in Study ARQ-151-101

In Study ARQ-151-101, the percent change from baseline in the primary endpoint (TPSS x TPA) was statistically significantly different (ARQ-151 0.15%: p<0.01; ARQ-151 0.5%: p<0.01) from vehicle for both active doses of ARQ-151 after 2 weeks of treatment and the product of plaque area and severity was reduced by >65% from baseline for both active dose groups after 4 weeks of treatment.

Safety

The incidence of TEAEs was comparable to vehicle for both doses (40.0% of subjects treated with 0.5% ARQ 151 vs. 25.0% of subjects treated with 0.15% ARQ-151 vs. 35.5% of subjects treated with vehicle), and all TEAEs were predominantly mild or moderate in severity. There were no SAEs and no discontinuations due to TEAEs. There was also none of the application site adverse reactions that are commonly associated with many other topical psoriasis treatments, and no evidence of the gastrointestinal side effects commonly seen with oral administration of roflumilast or other oral PDE4 inhibitors.

While there were no adverse side effects or tolerability issues with ARQ-151 identified during study ARQ-151-101, systemic exposure seen in the study was higher than predicted by our pre-clinical pharmacokinetic experiments. We therefore elected to reduce the maximum concentration from 0.5% roflumilast to 0.3% roflumilast for subsequent development.

Ongoing and Upcoming Trials

ARQ-151-202 Study

Subjects who completed 12 weeks of double-blind treatment in the ARQ-151-201 study were eligible to roll over to an open label long-term safety study, which is ongoing. In this study, all subjects are receiving 0.3% ARQ-151 topical cream once daily for 52 weeks. 231 subjects from Study ARQ-151-201 elected to roll over to the ARQ-151-202 study. In addition, 102 new subjects, who had not participated in the ARQ-151-201 study, were enrolled in Study ARQ-151-202. The primary endpoints of this study are the occurrence of TEAEs and the occurrence of SAEs. Study ARQ-151-202 is fully enrolled and ongoing, with topline results expected in the first half of 2021. We believe this study will fulfill regulatory submission requirements for 12 month safety data.

Phase 3 Program: ARQ-151-301 (DERMIS-1) Study and ARQ-151-302 (DERMIS-2) Study

We are conducting a Phase 3 clinical program for ARQ-151 consisting of three trials, including two ongoing identical multi-national, multi-center, double-blind, vehicle-controlled Phase 3 clinical trials (ARQ-151-301 and ARQ-151-302) to support registration with the FDA. In these studies, which we refer to as the “Trial of P***DE***4 inhibition with ***R***oflumilast for the ***M***anagement of Plaque Psoriasi***s***” (DERMIS-1, DERMIS-2), we plan to enroll a total of 800 mild-to-severe plaque psoriasis patients (400 patients per study) for 8 weeks of once daily treatment with ARQ-151 0.3% cream or matching vehicle to demonstrate the superiority of ARQ-151 treatment compared to vehicle. Randomization will be in a 2:1 ratio of active drug to vehicle.

These two trials will randomize patients ages 12 and above with plaque psoriasis covering between 2% and 20% BSA. The primary efficacy endpoint is the percentage of subjects attaining IGA Success at week 8, defined as a score of “clear” or “almost clear” PLUS a two-point improvement from baseline on the IGA scale at week 8. Multiple secondary endpoints will also be evaluated, including PASI-75, PASI-90, I-IGA in subjects with intertriginous plaques, WI-NRS in subjects with pruritus, and PSD. At the end of the 8-week treatment period, a proportion of patients will be eligible to roll over into the ARQ-151-306 (DERMIS-OLE) study.

Based on our positive October 2019 End-of-Phase 2 meeting with the FDA, we believe the design of the DERMIS-1 and DERMIS-2 studies will support the NDA submission of ARQ-151 for plaque psoriasis. We believe that if the results from DERMIS-1 and DERMIS-2 are positive, we will have sufficient efficacy data for the registration with the FDA of ARQ-151 for the treatment of plaque psoriasis, including psoriasis in intertriginous regions. We intend to use the results from DERMIS-1 and DERMIS-2, supported by the chronic treatment results from the ARQ-151-202 and ARQ-151-306 studies to support recommendations for long-term use. Safety data from Study ARQ-151-202, supplemented with data from Studies ARQ-151-101, ARQ-151-201, ARQ 151-107, ARQ-154-204, ARQ-151-301, ARQ-151-302, and ARQ-151-306, will form the basis for our Integrated Safety Summary that will be required by the FDA at the time of submission. Because we are collecting 12-month exposure data from Study ARQ-151-202, we do not believe we will need any additional long-term safety studies in Phase 3.

ARQ-151-306 (DERMIS-OLE) Study

A portion of subjects who complete 8 weeks of double-blind treatment in the DERMIS-1 and DERMIS-2 studies are eligible to roll over to the ongoing open label extension study, DERMIS-OLE. In this study, all subjects will receive 0.3% ARQ-151 topical cream for 24 weeks. Up to 250 subjects from DERMIS-1 and DERMIS-2 will be

eligible to enroll in DERMIS-OLE. The primary endpoints of this study are the occurrence of TEAEs and the occurrence of SAEs.

ARQ-151-107 Study

This is a phase 1, open label, single arm study in which 0.3% ARQ-151 topical cream will be applied for 2 weeks to adolescent and adult subjects under maximal usage conditions. Approximately 16 subjects will be enrolled. Body surface area involved will be at least 10% in adolescent subjects and at least 20% in adult subjects. The primary objective of this study is to evaluate the systemic exposure and characterize the plasma pharmacokinetic profile of 0.3% ARQ-151 topical cream.

Atopic Dermatitis

Completed Trials

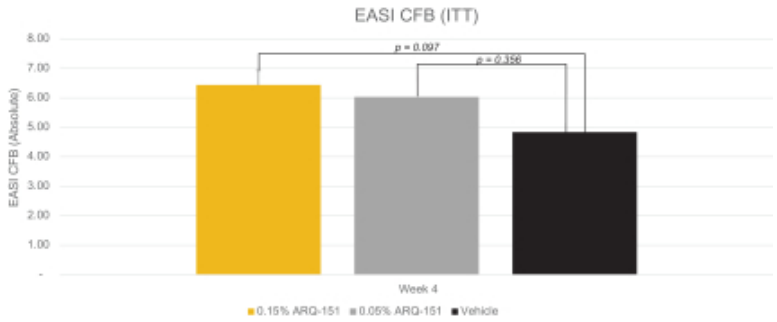
ARQ-151-212

The most recent study completed with ARQ-151 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% body surface area (BSA) were randomized to receive once daily topical applications for 4 weeks of: (1) ARQ-151 0.15% cream, or (2) ARQ-151 0.05% cream, or (3) vehicle. The goals of this small proof of concept study were to establish whether ARQ-151 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 ARQ-151 0.15% arm, 91% in the ARQ-151 0.05% arm, and 93% in the vehicle arm.

Primary Endpoint

The primary efficacy endpoint of our Phase 2 proof of concept study was the mean change from baseline, or CFB, in the EASI Total Score at week 4.

As shown in the graph below, neither dose reached statistical significance on the primary endpoint of mean CFB in EASI at week 4, although ARQ-151 0.15% showed a trend towards significance, with a mean improvement of 6.4 on the EASI score compared to 4.8 in patients treated with vehicle (p = 0.097).



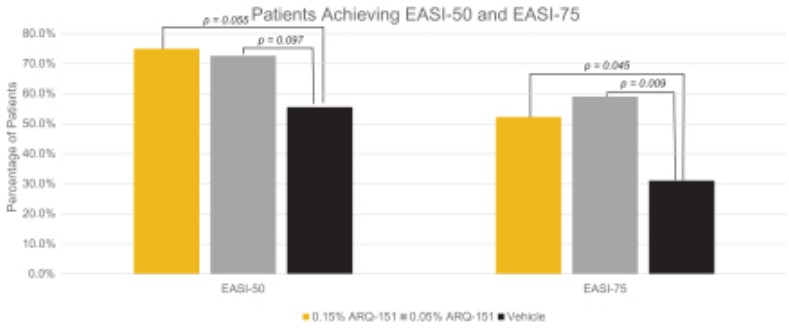
Secondary Endpoints

Secondary endpoints for our Phase 2 proof of concept study included:

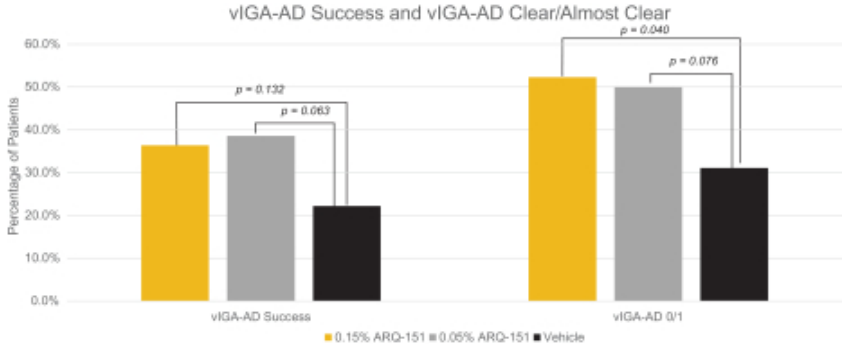
- Percent change from baseline in EASI Total Score at weeks 1, 2 and 4; and
- The percentage of patients attaining a 50% or 75% reduction from baseline on their EASI score (EASI-50, EASI-75) at weeks 1, 2 and 4.

On the secondary endpoint of mean percent change from baseline on EASI, ARQ-151 0.15% demonstrated a statistically significant improvement versus vehicle at week 4 (72.3% versus 55.8%, p = 0.049), and ARQ-151 0.05% showed a trend toward significance at week 4 (69.4% versus 55.8%, p = 0.164). There was also a trend toward significance in the percentage of patients treated with both strengths who achieved a 50% improvement in

EASI score (EASI-50) at 4 weeks compared to patients treated with vehicle (75% on ARQ-151 0.15% and 73% on ARQ-151 0.05% versus 56% on vehicle, p = 0.055 and p = 0.097 respectively). Statistically significantly more active drug treated patients achieved a 75% improvement in EASI score (EASI-75) at 4 weeks (52% on ARQ-151 0.15% (p = 0.045) and 59% on ARQ-151 0.05% (p = 0.009)) as compared to vehicle (31%).



On the Validated Investigators Global Assessment – Atopic Dermatitis, or vIGA-AD, a pre-specified exploratory endpoint, ARQ-151 0.15% also demonstrated statistically significant improvement versus vehicle in the percentage of patients achieving clear or almost clear at weeks 2 and 4 (week 4: ARQ-151 0.15%: 52.3% versus vehicle: 31.1%; p = 0.040), and showed a trend towards significance on the likely registrational endpoint of vIGA Success, defined as clear or almost clear PLUS a two point change, with AQR-151 0.15%: 36.4% versus vehicle: 22.2% (p = 0.132). ARQ-151 0.05% approached a statistically significant improvement versus vehicle on vIGA-AD Success at week 4 (38.6% versus 22.2%, p = 0.063), and showed a trend towards significance on vIGA-AD clear or almost clear at week 4 (50.0% versus 31.1%, p = 0.076).



In published data from third party clinical trials involving the approved PDE-4 inhibitor crisaborole (Eucrisa), the medium-potency steroid triamcinolone cream 0.1%, the developmental JAK inhibitors ruxolitinib and delgocitinib (JTE-052), and the developmental AHR agonist tapinarof, these drugs reported IGA Success rates in AD after four weeks of treatment of 31% to 33%, 26%, 38%, 10% and 38%, respectively. Based on a retrospective post-hoc cross-trial comparison that we compiled based on published data and our Phase 2 proof of concept study, we believe that ARQ-151 is likely to demonstrate similar mean IGA Success to these approved and in development AD therapies. The results of this retrospective post-hoc cross-trial comparison may not be directly comparable, as they are not from a single head-to-head clinical trial. Further, while we believe this data is useful in informing the design of future clinical trials and potential for ARQ-151, cross-trial comparisons involve the inherent bias of post-hoc manipulation of data and choice of analytical methods, as well as methodological issues surrounding heterogeneity among studies contributing to the analyses; therefore, it is important to view such results in light of the totality of all available information, such as individual study results on pre-specified analyses of endpoints. This cross-study comparison will not be used to support regulatory filings for ARQ-151.

Safety

In Study ARQ-151-212, ARQ-151 was well-tolerated by the subject population. The table below summarizes TEAEs in the study.

Table: Treatment-Emergent Adverse Events in ARQ-151-212

	ARQ-151 Cr 0.15% (N=45)	ARQ-151 Cr 0.05% (N=46)	Vehicle (N=45)
Subjects with any TEAE	12 (27%)	10 (22%)	6 (13%)
Number of TEAEs	16	16	8
Subjects with any Tx-Related TEAE	0	2 (4%)	2 (4%)
Number of Related TEAEs	0	2	2
Subjects with any SAE	0	1 (2%)(a)	0
Number of SAEs	0	1	0
Subjects who discontinued Study Drug due to AE	0	1 (2%)	1 (2%)
Subjects who discontinued Study due to AE	0	1 (2%)(b)	1 (2%)(c)

(a) One subject in the ARQ-151 0.05% group experienced a spinal cord compression related to a motor vehicle accident. The investigator deemed the AE not to be treatment related.
(b) One subject in the ARQ-151 0.05% group discontinued from the study due to an adverse event of "application site pain".
(c) One subject in the vehicle group discontinued from the study due to an adverse event of "dermatitis atopic".

Consistent with our experience in psoriasis, the incidence of AEs of special interest, such as the application site adverse reactions that are commonly associated with many other topical atopic dermatitis treatments or the gastrointestinal side effects commonly seen with oral administration of roflumilast or other oral PDE4 inhibitors, was also low throughout this study:

- Adverse events at the site of application were uncommon, and were balanced across groups (ARQ-151 0.15% = 0%, ARQ-151 0.05% = 4%, vehicle 4%), and only one patient on active treatment discontinued due to application site reactions.
- Rates of gastrointestinal AEs were low and balanced across groups (ARQ-151 0.15% = 2%; ARQ-151 0.05% = 2%; Vehicle = 4%);
- There was no evidence of unintentional weight loss (one subject on ARQ-151 0.05% experienced > 5% weight loss, but this was intentional and associated with diet and a fitness plan).

We believe the consistent evidence of symptomatic improvement demonstrated by both strengths of ARQ-151 across endpoints, as well as the improvement in atopic dermatitis demonstrated on both doses in this small proof-of-concept study provide evidence of the ability of ARQ-151 to treat the signs and symptoms of atopic dermatitis. Additionally, this study provided valuable insights into the safety and tolerability of ARQ-151 in this population, an especially important consideration because the majority of AD 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 ARQ-151 in atopic dermatitis. We plan to initiate a Phase 2b study in children, adolescents and adults with atopic dermatitis in the second half of 2020, following the completion of the ongoing pediatric atopic dermatitis PK study (Study ARQ-151-105).

ARQ-151-102 (Phase 1 Study)

The ARQ-151-102 was a single-site, open label Phase 1 study of the pharmacokinetics and safety of ARQ-151 in atopic dermatitis, in which 16 adults with mild to moderate atopic dermatitis covering between 4% and 8% BSA were treated for 15 days with: (1) 0.15% ARQ-151 topical cream, or (2) 0.05% ARQ-151 topical cream once daily. The primary focus of the study was to evaluate pharmacokinetics, safety and tolerability. Change from baseline in area of atopic dermatitis lesions was also measured. The study found that systemic exposure upon topical application of ARQ-151 at the same concentration and over the same BSA was similar in atopic dermatitis subjects and in psoriasis subjects. This suggests that the side effect profile and tolerability of ARQ-151 in atopic dermatitis may be similar to that seen in psoriasis. This is an important finding, as the damaged skin barrier in atopic

dermatitis patients may lead to increased systemic drug exposure with some therapies. In study ARQ-151-102, ARQ-151 was well-tolerated by the subject population, with no SAEs or discontinuations due to AEs during the study, and no evidence of irritation in any subject. The mean percent BSA involvement decreased from 6.1% in the 0.15% group and 5.8% in the 0.05% group at baseline to 3.1% and 2.6%, respectively, at Week 2, reflecting reductions of 49% and 55%. While there was no vehicle control in this study, we believe these results suggest that ARQ-151 may provide symptomatic improvement in the treatment of atopic dermatitis.

Ongoing Trials

ARQ-151-105 Study

The ARQ-151-105 study is a multi-center, open-label Phase 1 study of ARQ-151 in adolescent and pediatric subjects with mild to moderate atopic dermatitis, in which approximately 22 subjects between the ages of 2 and 17 years of age with atopic dermatitis covering between 1.5% and 35% BSA will receive ARQ-151 0.15% for 4 weeks. The primary endpoints of the study will be the pharmacokinetics of ARQ-151 as well as the safety and tolerability of ARQ-151 in this population. This study is designed to support the inclusion of pediatric and adolescent subjects in future clinical trials of ARQ-151 in atopic dermatitis.

ARQ-154

Overview

We are also developing ARQ-154, a foam formulation of ARQ-151 for the treatment of scalp psoriasis and seborrheic dermatitis. ARQ-154 contains roflumilast, the same highly potent and selective PDE4 inhibitor found in ARQ-151, and is nearly identical to ARQ-151, with all ingredients in ARQ-154 being the same as those in ARQ-151, other than reduced oil content and the addition of a propellant in the can to create the foam. We have initiated a Phase 2 proof of concept study for ARQ-154 in seborrheic dermatitis and a Phase 2b study in scalp psoriasis.

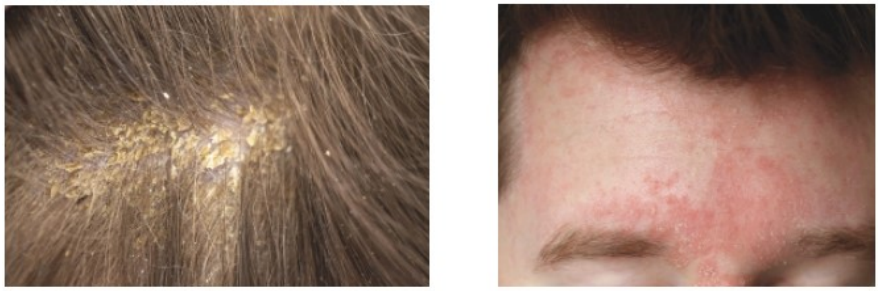
Product Profile and Differentiation

ARQ-154 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. ARQ-154 will not stain clothing or bedding, and does not have an unpleasant smell. ARQ-154 is designed for simple once-a-day application and neither burns nor stings on application. We believe that ARQ-154 has the potential to offer physicians and patients a highly differentiated clinical profile that is ideally suited to address unmet needs in the topical treatment of scalp psoriasis and seborrheic dermatitis.

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 formulations suitable for treating areas of the body affected by seborrheic dermatitis, including shampoos, foams, gels, and creams. 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, such as skin atrophy (thinning), telangiectasias (spider veins), folliculitis (inflammation of the hair follicle), and hypertrichosis (abnormal hair growth), physicians try to limit duration or avoid steroid therapy. The eyebrows and nasolabial folds are the most common sites of seborrheic dermatitis on the face. Their proximity to the eyes and the known association of steroid use with the development of cataracts and glaucoma add to physicians' apprehension in prescribing topical steroids for seborrheic dermatitis.
- **TCIs** are also 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. Many doctors are more comfortable using these drugs compared to steroids, especially on the face and around the eyes. 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, because TCIs are >800 Da in molecular weight, and since seborrheic dermatitis does not have a skin permeability defect, 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. This treatment resistant population represents a key opportunity for ARQ-154. Additionally, physicians are wary of using steroids on the face due 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. Therefore, in addition to the opportunity in treatment resistant patients, we believe ARQ-154 may be an option for some patients as a first-line therapy, especially patients with involvement of the face.

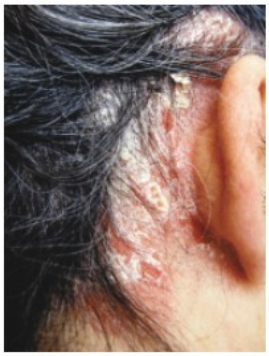
We believe physicians are seeking new therapies for seborrheic dermatitis that provide more symptomatic improvement than the current treatment paradigm, especially in those patients with an inadequate response to existing therapies. Furthermore, we believe an unmet need exists for an agent that not only provides the ability to be used chronically with a low risk of side effects, but also the ability to use on the face and near the eyes with a low

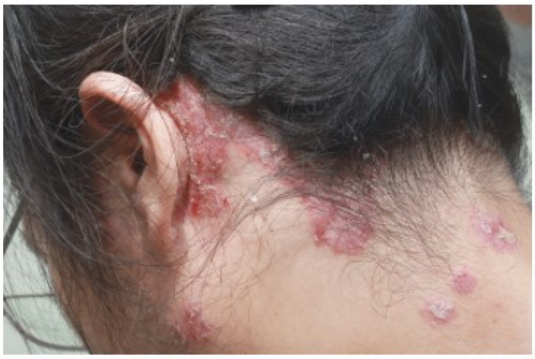
risk of ocular side effects. Given most patients suffering from seborrheic dermatitis have scalp involvement, we believe a formulation suitable for treating hair-bearing areas of the scalp is essential.

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 given the plaques are identical to the plaques in other body areas. Both biologics and systemic treatments will improve scalp psoriasis but suffer from the same limitations as in plaque psoriasis. Additionally, there is no evidence that adoption is greater in scalp psoriasis patients than other psoriasis patients.

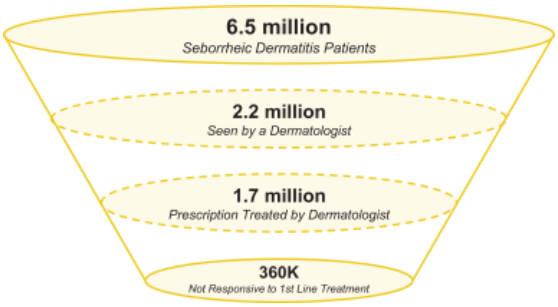
High-potency steroids and vitamin D3 analogs, topical agents that provide symptomatic improvement in plaque psoriasis, also provide symptomatic improvement in scalp psoriasis. However, due to the hair on most scalp psoriasis patients' scalps, lotions, creams and ointments are not appropriate for use on the scalp because of the difficulty of delivering the drug to the scalp. The negative impact on hair appearance can also affect patient compliance. A number of alternative formulations have been developed, such as solutions, suspensions, foams, or shampoos, containing high-potency steroids, vitamin D3 analogs, or a combination of the above. However, these formulations are also not ideal as the solutions and suspensions often run down patients' faces or into their ears, and some foam formulations are too greasy upon application. Other foam formulations melt upon application to the fingers before they can be applied to the scalp. More importantly, these formulations have the same risk of side effects and tolerability issues as their cream, ointment, and lotion counterparts. Physicians are especially concerned about the use of steroids to treat scalp psoriasis due to the potential for steroid exposure in the eye, and the resulting increased risk of cataracts and glaucoma.

We believe physicians are seeking a novel topical treatment for scalp psoriasis with the same characteristics as an ideal plaque psoriasis treatment (namely rapid onset, symptomatic improvement of a high-potency steroid, ability to use chronically with a low risk of side effects, no risk of rebound or tachyphylaxis, and ability to use in the periocular area with a low risk of side effects), but in a formulation that is convenient to use on hair-bearing areas of the scalp.

Our Market Opportunity

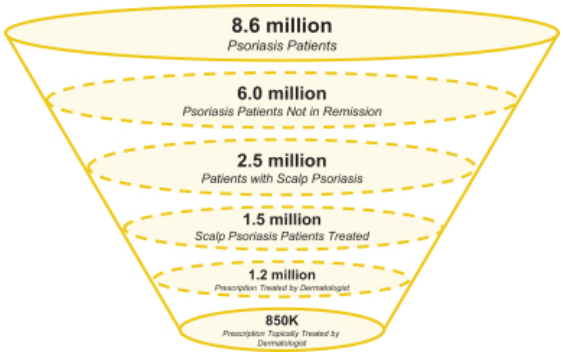
Seborrheic Dermatitis

We believe there is a significant market opportunity for us to capture within seborrheic dermatitis. As depicted below, we estimate there are approximately 6.5 million patients in the United States with seborrheic dermatitis, of which 2.2 million patients are treated by a dermatologist. Approximately 1.7 million patients receive prescription treatment for their seborrheic dermatitis from a dermatologist, and about 360,000 of those patients have an inadequate response to existing treatments, and thus would be the most likely candidates for a product like ARQ-154. We believe ARQ-154 may also be a first-line option for some of the other approximately 1.3 million patients treated by a dermatologist, especially due to concerns with steroid use in patients with involvement of the face. There is an even larger opportunity in the primary care setting that we may pursue through commercial partnerships.



Scalp Psoriasis

We believe there is a significant market opportunity for us to capture within scalp psoriasis. As depicted below, we estimate that of the 8.6 million psoriasis patients in the United States, approximately 2.5 million patients have active disease with involvement of the scalp. Of the population with scalp psoriasis, approximately 1.5 million patients are treated, with approximately 82% treated by dermatologists, and some 850,000 patients are treated with topical prescriptions from dermatologists.



ARQ-154 Clinical Development

We have initiated a Phase 2 proof of concept study for ARQ-154 in seborrheic dermatitis, and a Phase 2b study in scalp psoriasis.

Clinical Development Plan

ARQ-154-203 (Phase 2 Proof of Concept Study)

Study ARQ-154-203 is a multi-center, multi-national, double-blind, vehicle-controlled Phase 2 proof of concept study, in which approximately 185 adolescents (ages 12 and above) and adults with seborrheic dermatitis covering up to 20% BSA will be randomized to receive 8 weeks of (1) 0.3% ARQ-154 topical foam once daily, or (2) matching vehicle once daily. Randomization will be 2:1, active to vehicle. The primary efficacy endpoint will be the percentage of patients with an IGA score of “clear” or “almost clear” PLUS a 2-grade improvement from baseline

at week 8. The ARQ-154-203 study began enrollment November 2019, and we expect results from this study by the second half of 2020. If the results from the ARQ-154-203 study are positive, we expect to continue the development of ARQ-154 for the topical treatment of seborrheic dermatitis.

ARQ-154-204 (Phase 2b Study)

Study ARQ-154-204 is a multi-center, multi-national, double-blind, vehicle-controlled Phase 2b study, in which approximately 300 adolescents (ages 12 and above) and adults with scalp psoriasis covering at least 10% of the total scalp and total psoriasis involvement in all body areas of up to 25% BSA will be randomized to receive 8 weeks of (1) 0.3% ARQ-154 topical foam once daily, or (2) matching vehicle once daily. Randomization will be 2:1, active to vehicle. The primary endpoint of the trial is achievement of an Investigator Global Assessment Scale score of “clear” or “almost clear” PLUS a 2-grade improvement from baseline on the scalp, S-IGA at week 8. Multiple secondary endpoints will also be evaluated. We expect to report topline results from this study Q4 2020/Q1 2021. If the results from the ARQ-154-204 study are positive, we expect to continue the development of ARQ-154 for the topical treatment of scalp psoriasis.

ARQ-252

Overview

ARQ-252 is our small molecule inhibitor of JAK1 that we are developing for hand eczema and vitiligo. We plan to initiate a Phase 2b study of ARQ-252 in adult patients with hand eczema in the first half of 2020, with topline data expected in second half of 2021. We also plan to initiate a Phase 2a study of ARQ-252 in vitiligo in the second half of 2020.

In January 2018, we signed the Hengrui License Agreement for an option to an exclusive license to the active pharmaceutical ingredient in ARQ-252 for all topical dermatological uses in the United States, Canada, Europe and Japan. We exercised our exclusive option in December 2019 and also contemporaneously amended the agreement to expand the territory to additionally include Canada. 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.

Mechanism of Action

JAK1 is one of the janus family of non-receptor protein tyrosine kinases (JAKs), including JAK1, JAK2, and JAK3, and tyrosine kinase type 2, or Tyk2. Collectively, these kinases are involved in cell growth, survival, development, and differentiation of a variety of cells; specifically, JAK1, JAK3, and Tyk2 are critically important for immune cells and JAK2 is critically important for hematopoietic cells. JAK1, JAK3 and Tyk2 all play key roles in regulation of immune function and inflammation, and genetic mutations of these three kinases result in severe clinical immunodeficiencies such as severe combined immune-deficiency syndrome and autosomal recessive hyperimmuno-globulin E syndrome. Inhibitors of JAK1 and/or JAK3, and more recently Tyk2, have been shown to provide symptomatic improvement for a wide range of immunologically-driven diseases including rheumatoid arthritis, psoriasis, psoriatic arthritis, Crohn’s disease, ulcerative colitis, alopecia areata, and atopic dermatitis.

A wide range of receptors involved in hematopoietic cell development, including erythropoietin, thrombopoietin, and granulocyte-macrophage colony-stimulating factor, or GM-CSF, rely on JAK2 signaling. Unsurprisingly, genetic mutations of JAK2 result in myeloproliferative disorders, and JAK2 inhibition has been shown to provide symptomatic improvement as a therapeutic option for myelofibrosis, which often involves overexpression of JAK2, and other hematological diseases.

Topical JAK inhibitors have been shown to provide significant symptomatic improvement in the treatment of atopic dermatitis and eczema, and more recently, in vitiligo, although they are much less effective in psoriasis. The principal challenge with JAK treatment is the safety profile of JAK inhibitors. Inhibition of JAK2 may lead to

neutropenia, thrombocytopenia, anemia, or increased thromboembolism. Inhibition of JAK1 may lead to serious or opportunistic infections, tuberculosis, or lymphoma and other malignancies. Topical administration may reduce these risks substantially compared to oral administration of JAK inhibitors due to the reduced systemic exposure through topical administration.

Product Profile and Differentiation

ARQ-252 is topical cream formulation of a potent and highly selective small molecule inhibitor of JAK1. As seen in the table below, ARQ-252 has been observed in a preclinical study conducted by us to be highly selective to JAK1 over JAK2, in stark contrast to ruxolitinib, the furthest advanced topical JAK inhibitor in U.S. development for atopic dermatitis and vitiligo. In the table below, a lower IC50 value, a common measurement of drug potency, indicates a lesser amount is required to inhibit the various JAK subtypes. The ARQ-252 JAK1:JAK2 IC50 ratio is 23.5:1, compared to ruxolitnib's JAK1:JAK2 IC50 ratio of 2.6:1. 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.

JAK Inhibitor Potency in Cell-based Assay System

	JAK1/3 Inhibition						JAK2 Inhibition	
	IL-2		IL-4		IL-6			
IC50 (μM)	**CD-4**	**CD-8**	**CD-4**	**CD-8**	**CD-4**	**CD-8**	**GM-CSF**	
ARQ-252	1.15	1.05	2.29	1.39	5.22	1.66	50	*
Ruxolitinib	1.48	1.25	3.24	1.87	4.49	1.50	6.08	

* A value of 50 μM was used as the IC50 value for the purpose of assigning a ratio, since 50% inhibition of JAK2 was not reached. The average percentage inhibition measured in the GM-CSF assay was 23.5% at 20 μM. While 50 μM was used, we believe that the IC50 value is greater than 50 μM, but likely < 100 μM.

Additionally, in mid-2019, Hengrui completed a Phase 2b study in rheumatoid arthritis that used the same active pharmaceutical ingredient as in ARQ-252 but dosed orally. The results from this study confirmed that this active pharmaceutical ingredient is a highly potent inhibitor of JAK1 based on the drug's impact on rheumatoid arthritis, and it was generally well tolerated at exposures well above those expected with topical administration of ARQ-252.

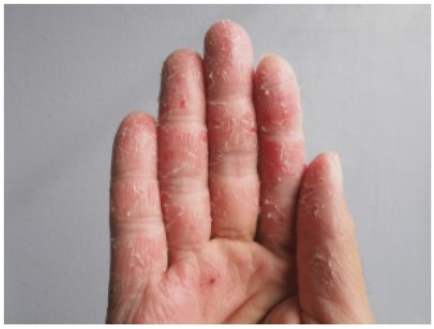
We believe that ARQ-252 could offer a best-in-class topical JAK inhibitor, with a more favorable tolerability profile than other topical JAK inhibitors due to its selectivity to JAK1 over JAK2, robust symptomatic improvement due to its high-potency against JAK1, and a convenient and patient-friendly cream formulation.

Hand Eczema

Hand Eczema Background

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. It is the most common skin disease affecting the hands, with prevalence estimated at up to 2.5% of the population. Hand eczema is 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 a diverse syndrome, incorporating dyshidrotic eczema, an immune disease possibly related to atopic dermatitis; irritant contact dermatitis of the hands, which is caused by occupational irritants such as chemicals; allergic contact dermatitis of the hands, which is caused by an allergic reaction; atopic hand dermatitis, which is atopic dermatitis occurring on the hands, and hyperkeratotic hand dermatitis, which are thickened, scaly, red plaques, similar to psoriasis, on the hands. 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, particularly because it is more difficult to deliver drugs topically on the palms of the hand due to the thicker skin that can be up to ten times thicker than skin from other body areas, which inhibits drug absorption. 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 recently demonstrated proof-of-concept for their JAK inhibitor, delgocitinib, in an ointment form in a Phase 2a study of hand eczema. They are currently conducting a dose-ranging Phase 2b study for a cream formulation of delgocitinib.

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. Because hand eczema is painful and can be debilitating, there is a high sense of urgency to treat effectively. Physicians and patients would like a new therapy that provides symptomatic improvement with a low risk of side effects and favorable tolerability profile.

Other Indications

Vitiligo

Vitiligo is a disfiguring disease that causes the complete loss of skin color in blotches or patches in a symmetrical distribution. The disease is caused by the localized complete destruction by the immune system of melanocytes, the skin cells that produce skin pigmenting melanin, resulting in complete depigmentation in the affected area. We plan to initiate a Phase 2a clinical trial in the second half of 2020. Ruxolitinib, another topical JAK inhibitor, has shown some promising results in the treatment of vitiligo, although there are clearly opportunities to improve on the profile shown with that other agent thus far.

ARQ-252 Clinical Development

We are planning to initiate two clinical studies with ARQ-252 in 2020, one in hand eczema and one in vitiligo.

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

We plan to initiate our first study with ARQ-252, the ARQ-252-205 Study, in the first half of 2020. This study will be a multi-center, multi-national, double-blind, randomized, vehicle-controlled Phase 2b study, in which 215 adults with chronic hand eczema will be 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 will be an IGA of “clear” or “almost clear” PLUS at least a 2-point improvement from baseline at week 12.

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

We are currently developing the protocol for a Phase 2a study, ARQ-252-213, to evaluate ARQ-252 for the topical treatment of vitiligo. JAK1 as a target for vitiligo has been validated by Incyte's recent results on topical ruxolitinib. Given the results of the ruxolitinib vitiligo study, this study will likely concentrate on vitiligo of the face, which causes psychosocial problems for the afflicted person, and is also generally the anatomic area of disease most responsive to treatment because of the proximity of hair follicles which help in the repigmentation process. This study will be a multi-center, multi-national, double-blind, randomized, vehicle controlled Phase 2a study in adults with vitiligo. The primary efficacy endpoint will be percent improvement from baseline in the Face Vitiligo Area Scoring Index (F-VASI) score. We plan to start this study in the second half of 2020. If the results of the ARQ-252-213 study are positive, we plan to continue the development of ARQ-252 for the topical treatment of vitiligo.

ARQ-255

Overview

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 ARQ-151, including tapinarof, under development by Dermavant Sciences, 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 ARQ-151, 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 Dermira, Inc.

For hand eczema, our primary competitors include topical therapies such as branded and generic versions of clobetasol, such as Clobex, and generic versions of betamethasone dipropionate. The only other prescription product candidate we are aware of under development for the treatment of hand eczema that would compete with ARQ-252 is delgocitinib, which showed proof-of-concept in a Phase 2a 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. 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 March 2, 2020, we own or have an exclusive license to ten issued U.S. patents and seven issued foreign patents, which include granted European patent rights that have been validated in various 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:

- **ARQ-151 & ARQ-154**: As of March 2, 2020, we own five issued U.S. patents, one issued Canadian patent, one issued Japanese patent, four pending U.S. patent applications and 12 pending foreign applications (one each in China, Hong Kong, Japan, Mexico, New Zealand, India, Australia, Europe, Israel, and Brazil, and two under the Patent Cooperation Treaty), relating to ARQ-151 and ARQ-154. The issued U.S. patent that we have licensed from AstraZeneca claiming a composition of matter encompassing roflumilast, the active pharmaceutical ingredient in ARQ-151 and ARQ-154, expired on January 27, 2020. Data exclusivity for roflumilast is expected to expire on January 23, 2021. Our issued patents relating to ARQ-151 and ARQ-154 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 ARQ-151 and ARQ-154 will expire not earlier than June 2037 (excluding any potential PTE).
- **ARQ-252 & ARQ-255**: As of March 2, 2020, 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 AB

In July 2018, we entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca AB, or 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 969,117 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 ARQ-151 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 European Union (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 non-exclusive 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 U.S. Food and Drug Administration, or FDA, and other governmental authorities. The Federal Food, Drug, and Cosmetic Act, or FDC 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 new drug applications, 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 application, or 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 multicenter 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, currently exceeding $2,940,000 for Fiscal Year 2020. The manufacturer and/or sponsor under an approved NDA is also subject to an annual program fee, currently exceeding $325,000 for each prescription drug product for 2020. 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, or PDUFA, 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 new drug application, 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 patent term extension 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 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 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. The ACA amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. 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.

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, the ACA amended the federal Anti-Kickback Statute such that a violation of that 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 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.

In addition, HIPAA, as amended by 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. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. 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, pursuant to the ACA, the CMS has issued a final rule that requires 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 first reports were due in 2014 and must be submitted on an annual basis. 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, 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 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% by the BBA, (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 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 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 Tax Cuts and Jobs Act of 2017, or TCJA, was enacted, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the 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. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and 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, including the BBA, will remain in effect through 2029 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.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the MMA changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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. At the federal level, the current U.S. presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the current U.S. presidential administration laid out the administration's "Blueprint" to reduce the cost of prescription medications while preserving innovation and cures. While HHS is soliciting feedback on some of these measures, other actions may be immediately implemented by HHS under existing authority. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, Congress and the current U.S. presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

Employees

As of December 31, 2019, we had 29 full-time employees. Of these full-time employees, 6 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.

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 2945 Townsgate Road, Suite 110, Westlake Village, California 91361, and our telephone number is (805) 418-5006. Our website address is www.arcutis.com. The information found on or accessible through our website is not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

Available Information

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

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, 2019 and 2018 was approximately $42.0 million and $19.3 million, respectively. As of December 31, 2019, we had an accumulated deficit of $66.3 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. We may never achieve profitability and, even if we do, we may not be able to sustain profitability in subsequent periods. We will continue to incur significant research and development and other expenses related to our ongoing operations and the development of our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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

Since our inception, we have invested substantially all of our efforts and financial resources in research and development activities, and we expect to continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates, ARQ-151, ARQ-154, 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, 2019, we had capital resources consisting of cash, cash equivalents and marketable securities of $101.3 million. Additionally, we received gross cash proceeds of $183.3 million in connection with our initial public offering in February 2020. Based on our planned operations, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations through 2021l. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

- the scope, progress, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our currently ongoing Phase 3 clinical trials of ARQ-151 in plaque psoriasis, our planned Phase 2b study of ARQ-151 in atopic dermatitis, our ongoing Phase 2 proof of concept study of ARQ-154 in seborrheic dermatitis, our currently ongoing Phase 2b study of ARQ-154 in scalp psoriasis, our planned Phase 2b study of ARQ-252 in hand eczema, our planned Phase 2a study of ARQ-252 in vitiligo and our formulation and preclinical efforts for ARQ-255 in alopecia areata;
- 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;
- the cost of building a sales force in anticipation of product commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the timing and amount of milestone payments due to AstraZeneca, Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, or any future collaboration or licensing partners upon the achievement of negotiated milestones;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products, if any.

Adequate additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis or on attractive terms, we may be required to reduce our workforce, delay, limit, reduce or terminate our research and development activities, preclinical studies, clinical trials or other development activities and future commercialization efforts, or grant rights to develop and market product candidates, such as ARQ-151, 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;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development, or failure to obtain such approvals;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on U.S. Food and Drug Administration, or FDA, guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies, which may include obligations to make significant upfront and milestone payments;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on CROs and third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates both within and outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements with respect to our product candidates;
- our ability to maintain and enforce our intellectual property position;
- costs related to and outcomes of potential litigation or other disputes in respect of our product candidates and our business;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

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

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

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot assure you of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this 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 ARQ-151, a potent PDE4 inhibitor topical cream for the treatment of plaque psoriasis and atopic dermatitis, and our additional product candidates ARQ-154, a topical foam formulation of ARQ-151 for the treatment of scalp psoriasis and seborrheic dermatitis, and ARQ-252, a potent and highly selective topical JAK1 inhibitor for the treatment of hand eczema, and ARQ-255, a potential topical treatment for alopecia areata. We currently do not have a drug discovery or research and development effort to discover new product candidates, and we have no intention to develop one. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of these current product candidates. We expect to conduct most of our clinical trials in the United States and Canada, with current limited plans for clinical trials in Australia and the European Union. We currently anticipate seeking regulatory approvals in the United States and Canada, but may in the future be subject to additional foreign regulatory authorities and may out-license our product candidates or approved products, if any, in additional foreign markets. In the future, we may also become dependent on other product candidates that we may acquire or in-license. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate, including as a result of the impact of the COVID-19 outbreak, and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our lead product candidates or any future product candidates or approved products, if any;
- the willingness of physicians and patients to utilize or adopt our product candidates;

- the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates to remain in good standing with relevant regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, our Phase 2 proof of concept study in atopic dermatitis had a limited number of patients and it did not reach statistical significance for the primary endpoint or the secondary endpoint of IGA Success, which we expect will be the primary endpoint in any registrational trial, but did show nominal significance in certain secondary endpoints. While we believe this is evidence of the ability of ARQ-151 to treat the signs and symptoms of atopic dermatitis, these results may not be replicated or improved in later studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. For example, we are developing ARQ-154, including ongoing Phase 2 clinical trials in patients with seborrheic dermatitis and in patients with scalp psoriasis, based on our clinical experience with ARQ-151 in psoriasis. Despite our observations of ARQ-151 in a similar dermatological indication, ARQ-154 may not demonstrate comparable results in seborrheic dermatitis or scalp psoriasis. In addition, given its different formulation there is a risk that we select an incorrect dose for ARQ-154, as the clinical effect of ARQ-154 may differ from ARQ-151 at a similar dosing level or we may observe unexpected side effects not previously observed with ARQ-151.

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:

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

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

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

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

To gain approval to market our product candidates, we must provide the FDA and foreign regulatory authorities with preclinical and clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication applied for in the applicable regulatory filing. Product development is long, expensive and uncertain processes, and delay or failure can occur at any stage of any of our preclinical and clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical or clinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or

efficacy observations made in clinical studies, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

Our lead product candidate ARQ-151, and ARQ-154, its foam formulation, are currently in clinical development. Our product candidate ARQ-252 will soon enter clinical development for hand eczema and vitiligo. ARQ-255 is in formulation and preclinical development for the potential treatment of alopecia areata. We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize our lead product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions, including pricing approval in the European Union.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates is safe and effective for the requested indication;
- the FDA or other relevant foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our Phase 3 clinical trials of ARQ-151 for the treatment of plaque psoriasis;
- the FDA or other relevant foreign regulatory authorities may not find the data from preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products candidates outweigh their safety risks or that there is an acceptable risk-benefit profile;
- the results of our clinical trials may not meet the level of statistical significance or clinical meaningfulness required by the FDA or other relevant foreign regulatory authorities for marketing approval;
- the FDA's or the applicable foreign regulatory authority's requirement for additional preclinical studies or clinical trials which would increase our costs and prolong our development timelines;
- the FDA or other relevant foreign regulatory authorities may disagree with our interpretation of data or significance of results from the preclinical studies and clinical trials of any product candidate, or may require that we conduct additional studies;
- the FDA or other relevant foreign regulatory authorities may not accept data generated from our clinical trial sites;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact our clinical trials and ability to obtain market approvals;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant foreign regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant foreign regulatory authority, as the case may be, require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant foreign regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant foreign regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant foreign regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates;
- the FDA or other relevant foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant foreign regulatory authorities may change their approval policies or adopt new regulations.

- the FDA's or the applicable foreign regulatory authority's non-approval of the formulation, dosing, labeling or specifications;
- the FDA's or the applicable foreign regulatory authority's failure to approve the manufacturing processes of third-party manufacturers upon which we rely or the failure of the facilities of our third-party manufacturers to maintain a compliance status acceptable to the FDA or the applicable foreign regulatory authority; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

Certain of our primary and secondary endpoints in our clinical trials, including our currently ongoing Phase 3 clinical trials of ARQ-151 in plaque psoriasis, involve subjective assessments by physician and patients, which can increase the uncertainty of clinical trial outcomes. For example, one of the secondary endpoints requires patients to report pruritus (itching) as measured by the Worst Itch – Numeric Rating Scale and complete or deliver patient or caregiver reported outcomes over the course of our clinical trials. This and other assessments are inherently subjective, which can increase the variability of clinical results across clinical trials and create a significant degree of uncertainty in determining overall clinical benefit. Such assessments can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular patient, and from patient-to-patient and site-to-site within a clinical trial. In addition, frequent reporting requirements may lead to rating fatigue and a loss of accuracy and reliability of the data resulting from our clinical trials. Further, the FDA or comparable foreign regulatory authority may not accept such patient or caregiver reported outcomes as sufficiently validated. Accordingly, these subjective assessments can complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement and generally adversely impact a clinical development program by introducing additional uncertainties.

Patient reported outcome instruments, their use in our Phase 3 clinical trials of ARQ-151 and the inclusion of such data in the product labeling will depend on, but is not limited to, the FDA's review of the following:

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

Further, different results may be achieved depending upon the characteristics of the population enrolled in our studies and which analysis population is used to analyze results. For example, the primary endpoint in our Phase 3 clinical trials of ARQ-151 in plaque psoriasis is based on the percentage of patients achieving a score of "clear" or "almost clear" plus at least a 2-grade improvement from baseline on the 5 point Investigator's Global Assessment (or IGA) scale, referred to as "IGA Success". Success in our Phase 3 clinical trials, or other clinical trials with these or similar endpoints, requires the enrollment of patients with conditions that are severe enough to facilitate a two-grade improvement in the IGA scale, but not so severe that they cannot achieve a "clear" or "almost clear" in IGA score in light of the severity of their disease. It is therefore possible that we enroll patients with conditions so severe that they do not or are unable to realize an IGA of 0 (clear) or 1 (almost clear) during the period covered by the clinical trial. As a result, there is no guarantee that our Phase 3 clinical trials will produce the same statistically significant results in "IGA Success", which will serve as the primary endpoint, as our Phase 2b clinical trial, and there can be no guarantee that the characteristics of the population enrolled in our Phase 3 clinical trials does not adversely impact the results reported for such trial, any of which could have an adverse effect on our ability to secure regulatory approval for our product candidates.

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

We may not be able to initiate or continue clinical trials for ARQ-151 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 ARQ-151, ARQ-154, ARQ-252 and ARQ-255, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;

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

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

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

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

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

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

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

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

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

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

To date, we have completed two Phase 2 studies in plaque psoriasis and a Phase 2 proof of concept study in atopic dermatitis in ARQ-151, and have initiated a Phase 3 program in plaque psoriasis, which includes two registrational Phase 3 studies. We also anticipate commencing more advanced clinical trials of ARQ-151 in the treatment of atopic dermatitis. Failure to successfully complete, or delays in, our pivotal trials or related regulatory submissions would prevent us from or delay us in obtaining regulatory approval for our product candidates. In addition, it is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our applications that they are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept our applications or issue marketing authorizations for our product candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA for any other applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Additionally, similar risks could apply to receipt of marketing authorizations by comparable regulatory authorities in foreign jurisdictions.

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

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

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

- the safety, efficacy, risk-benefit profile and potential advantages compared to alternative or existing treatments, such as steroids topical treatments, oral treatments, and biologic injections for the treatment of psoriasis, which physicians may perceive to be adequately effective for some or all patients;
- side effects that may be attributable to our product candidates and the difficulty of or costs associated with resolving such side effects;
- limitations or warnings contained in the labeling approved for our product candidates by FDA or other applicable foreign regulatory authorities;
- any restrictions on the use of our products, and the prevalence and severity of any side effects;
- the content of the approved product label;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments and over-the-counter, or OTC treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies over existing therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement at any given price level of each of our product candidates;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of any of our product candidates.

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

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

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

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

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

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

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

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions in both the United States and in international markets. Third-party coverage and reimbursement for any of our product

candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

We currently have no 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 a sales and marketing organization. We do not currently have any infrastructure for the sales, marketing, or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

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

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

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

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

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

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

For example, upon regulatory approval from the FDA to commercialize ARQ-151 in the United States, but prior to commencement of commercialization or sales of ARQ-151, 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 ARQ-151 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., 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 ARQ-151, including topical tapinarof, under development by Dermavant Sciences, Inc., and PF-06700841, an oral Tyk2/JAK1 inhibitor under development by Pfizer, Inc.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc., and generic and branded versions of low to mid-potency steroids such as hydrocortisone and betamethasone; and the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with ARQ-151, including but not limited to: topical tapinarof and topical cerdulatinib, both under development by Dermavant Sciences, Inc., topical ruxolitinib, under development by Incyte Corporation, topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc., topical PF-06700841, a Tyk2/JAK1 inhibitor under development by Pfizer, Inc., topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, oral PF-04965842, under development by Pfizer Inc., oral upatacitinib, under development by AbbVie, Inc., and injectable lebrikizumab, under development by Dermira, Inc.

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

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, 2019, we had 29 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our lead product candidates or any future product candidates.

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

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

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

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

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

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by patents or other proprietary rights controlled by third parties;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

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 marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws (and other similar non-U.S. laws), if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. By way of example, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states as well as in non-U.S. jurisdictions. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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

We are exposed to the risk that our future commercial partners, as well as our employees and independent contractors, including principal investigators, consultants, suppliers, service providers and other vendors may

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

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

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

Risks Related to Our Reliance on Third Parties

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

We do not currently have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. Instead, we currently rely on single source third-party manufacturers to manufacture preclinical and clinical supplies of our product candidates and we intend to rely on third parties to produce commercial supplies of any approved product candidate. In the fourth quarter of 2019, we received a batch of our product candidate that we believe is representative of our anticipated early commercial batch requirements. However, as a late-stage company with no prior history of product

sales or commercialization of products, representative batches of our product candidate received to date may not represent what will be required to meet our future commercial requirements or be manufactured at scale.

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

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

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

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

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

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

Before beginning commercial manufacture of ARQ-151, ARQ-154, ARQ-252 or ARQ-255, the process and systems used in the manufacture of ARQ-151, ARQ-154, 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, ARQ-151, ARQ-154, 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 ARQ-151, ARQ-154, 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 ARQ-151, ARQ-154, 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.

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

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

Risks Related to Intellectual Property

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

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

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

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current licensors, or any future licensors or licensees may not be able to prepare, file and prosecute all

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

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

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

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

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

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- for some product candidates, including ARQ-151 and ARQ-154, 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 ARQ-151 and ARQ-154 with claims directed to, among other things, formulating roflumilast in combination with hexylene glycol are currently projected to expire on June 7, 2037 and the issued U.S. patents which we have exclusive rights to from Hengrui as a result of the exercise of our exclusive option with Hengrui in December 2019 for the amount of $1.5 million cash, related to the composition of matter of the active ingredient in ARQ-252 and ARQ-255 (or bisulfate or crystal forms thereof) are currently projected to expire between January 21, 2033 and October 15, 2035 unless a patent term extension is granted. Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of ARQ-151, ARQ-154, 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 ARQ-151, ARQ-154, 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 ARQ-151, ARQ-154, 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 ARQ-151, ARQ-154, ARQ-252 or ARQ-255.

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

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

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

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

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

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

The validity, scope and enforceability of any patents listed in the Orange Book that cover ARQ-151, ARQ-154, ARQ-252 or ARQ-255 can be challenged by competitors.

If ARQ-151, ARQ-154, ARQ-252 or ARQ-255 is approved by the FDA, one or more third parties may challenge the patents covering ARQ-151, ARQ-154, ARQ-252 or ARQ-255, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an abbreviated new drug application, or ANDA, for a generic drug bioequivalent to ARQ-151, ARQ-154, 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 ARQ-151, are currently projected to expire on June 7, 2037. Certain issued U.S. patents that we have licensed from Hengrui relating to, among other things, treatment of several diseases or disorders, including various cancers, allograft rejection, graft versus host disease, rheumatoid arthritis, atopic dermatitis, and psoriasis with SHR0302, or bisulfate and crystal forms thereof, are currently projected to expire beginning in 2033. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

Any regulatory approvals or other marketing authorizations we obtain for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or the conditions of approval or marketing authorization, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our drug product candidates, such as ARQ-151, ARQ-154, ARQ-252 and ARQ-255, which could include requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority authorizes our product candidates for marketing, the manufacturing

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

- limited daily trading volume resulting in the lack of a liquid market;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- regulatory, legal or political developments in the United States and foreign countries;
- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;
- the execution of our partnering and manufacturing arrangements;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the success of, and fluctuations in, the commercial sales any product candidates approved for commercialization in the future;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole, including as a result of market volatility related to the COVID-19 outbreak and global health concerns;
- 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.

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

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

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

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

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

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

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

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

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

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

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

As of February 10, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 48% of our voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position, including the ability to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of approximately 24.4 million shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

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

Our ability to utilize our net operating loss, or NOL, carryforwards and research and development income tax credit carryforwards may be limited.

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

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

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

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

- a classified board of directors with three year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our corporate headquarters are located in Westlake Village, California, where we lease approximately 4,741 square feet of office space. The current terms of our lease expire and in July 2021.

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 Nasdaq Global Select Market under the symbol “ARQT” since our initial public offering on January 31, 2020. Prior to that time, and during the year ended December 31, 2019, there was no public market for our common stock.

Holders

As of March 19, 2020, there were approximately 179 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 following table provides certain information as of December 31, 2019, with respect to all of our equity compensation plans in effect on that date:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity Compensation Plans Approved by Stockholders(1)	2,516,470	$ 3.47	1,550,150
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	**2,516,470**	**$ 3.47**	**1,550,150**

(1) Consists of the Arcutis Biopharmaceuticals, Inc. 2017 Equity Incentive Plan, as amended.

The 2020 Plan, which became effective upon the completion of the IPO on January 31, 2020, serves as the successor equity incentive plan to the Company's 2017 Plan and has 2,134,000 shares of common stock available for issuance, plus any reserved shares not issued or subject to outstanding grants under the 2017 Equity Incentive Plan.

The 2020 Equity Incentive Plan contains an “evergreen” provision, pursuant to which the number of shares of common stock reserved for issuance pursuant to awards under such plan shall be increased on the first day of each year beginning in 2021 and ending in 2030 equal to the lesser of (a) four percent (4%) of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year 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.

In addition, the Company adopted the 2020 ESPP, which became effective upon the completion of the IPO on January 31, 2020. 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 our board of directors; provided, however, no more than 5,265,000 shares of our common stock may be issued under the ESPP.

Recent Sales of Unregistered Securities

From January 1, 2019 through December 31, 2019, we sold and issued the following unregistered securities:

1. In October 2019, we issued an aggregate of 8,122,963 shares of its Series C convertible preferred stock at a purchase price of $11.63 per share for an aggregate gross purchase price of approximately $94.5 million, which converted automatically into one share of our common stock upon the completion of our initial public offering in January 2020. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act.

2. Prior to filing our registration statement on Form S-8 in January 2020, we granted stock options and stock awards to employees, directors and consultants under our 2017 Equity Incentive Plan covering an aggregate of 2,421,221 shares of common stock, at a weighted-average exercise price of $3.59 per share. Of these, options covering an aggregate of 44,984 shares were cancelled without being exercised. The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans.

3. Prior to filing our registration statement on Form S-8 in January 2020, we sold an aggregate of 13,245 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of $7,685. The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans.

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

Use of Proceeds

On January 30, 2020, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-235806 and File No. 333-236177), as amended, filed in connection with our initial public offering (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 fourth quarter of the year ended December 31, 2019.

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, 2019, 2018 and 2017, and the selected balance sheet data as of December 31, 2019 and 2018, 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,		
	2019	2018	2017
	(in thousands, except share and per share data)		
Statements of operations data:			
Operating expenses:			
Research and development	$ 36,522	$ 17,940	$ 3,411
General and administrative	6,610	1,795	695
Total operating expenses	43,132	19,735	4,106
Loss from operations	(43,132)	(19,735)	(4,106)
Other income (expense), net	1,136	480	(872)
Net loss	$ (41,996)	$ (19,255)	$ (4,978)
Net loss per share, basic and diluted[(1)]	$ (22.78)	$ (15.53)	$ (7.16)
Weighted-average shares used in computing net loss per share, basic and diluted[(1)]	1,843,213	1,239,689	695,305

(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,	
	2019	2018
	(in thousands)	
Balance sheet data:		
Cash, cash equivalents, and marketable securities	$ 101,265	$ 50,940
Working capital[(1)]	101,237	48,425
Total assets	107,012	51,098
Convertible preferred stock	166,491	72,252
Accumulated deficit	(66,272)	(24,276)
Total stockholders' deficit	(65,029)	(23,987)

(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 topical treatments with significant potential to address immune-mediated dermatological diseases and conditions, or immuno-dermatology. Our strategy is to identify and develop treatments against validated biological targets in dermatology that deliver a differentiated clinical profile that addresses major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product candidate, ARQ-151, is in Phase 3 clinical trials in plaque psoriasis. ARQ-151 is a topical cream formulation of roflumilast, a highly potent and selective phosphodiesterase type 4, or PDE4, inhibitor, which we are developing for the treatment of plaque psoriasis, including psoriasis in intertriginous regions such as the groin, axillae, and inframammary areas, as well as atopic dermatitis. In July 2018, we executed a licensing agreement with AstraZeneca AB, or AstraZeneca, for exclusive worldwide rights to all topical dermatological uses of roflumilast. We have successfully completed a Phase 2b study of ARQ-151 in plaque psoriasis, and, in August 2019, paid AstraZeneca the first milestone payment of $2.0 million that was earned upon the achievement of positive Phase 2 data for any AZ-Licensed Product (as defined in "—License Agreements—AstraZeneca License Agreement"). We have initiated three Phase 3 studies in plaque psoriasis, with topline data expected in the first half of 2021. We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, and expect to report topline data in the first half of 2021. We also completed a Phase 2 proof of concept study of ARQ-151 in atopic dermatitis and plan to initiate a Phase 2b study in the second half of 2020, with topline results expected in the second half of 2021. In addition, we are developing ARQ-154, a topical foam formulation of ARQ-151, and have initiated a Phase 2 proof of concept study in seborrheic dermatitis and a Phase 2b study in scalp psoriasis. We expect to report topline data in the second half of 2020 with respect to seborrheic dermatitis and in Q4 2020/Q1 2021 with respect to scalp psoriasis. Beyond this, in 2020, we also plan to initiate clinical studies of ARQ-252, a potent and highly selective topical janus kinase type 1, or JAK1, inhibitor for the treatment of hand eczema and vitiligo. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. In January 2018, we executed an exclusive option and license agreement with Jiangsu Hengrui Medicine Co., Ltd. of China, or Hengrui, to the active pharmaceutical ingredient in ARQ-252 and ARQ-255 for all topical formulations for dermatological uses in the United States, Europe and Japan. In December 2019, we exercised our exclusive option associated with this agreement, for which we made a $1.5 million cash payment, and also contemporaneously amended the agreement to expand the territory to additionally include Canada.

Since our inception in 2016, we have invested a significant portion of our efforts and financial resources in research and development activities. We have not generated any revenue from product sales and, to date, have funded our operations primarily with $162.5 million in net cash proceeds from private placements of our convertible preferred stock as of December 31, 2019. In February 2020, we received $183.3 million in gross cash proceeds related to our initial public offering. We have incurred net losses in each year since inception, including net losses of $42.0 million, $19.3 million and $5.0 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019 and 2018, we had an accumulated deficit of $66.3 million and $24.3 million, respectively, and cash, cash equivalents and marketable securities of $101.3 million and $50.9 million, respectively.

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

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

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. We do, however, believe that there will be an impact on the clinical development of our product candidates, which may include potential delays, halts or modifications to our ongoing and planned trials.

License Agreements

AstraZeneca License Agreement

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

We paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of our Series B Preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of ARQ-151 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. For more information, please see "Business—Exclusive License and Option Agreements."

Hengrui Exclusive Option and License Agreement

In January 2018, we entered into an exclusive option and license agreement, or Hengrui License Agreement, with Hengrui, whereby Hengrui granted us an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, and the European Union (including for clarity the United Kingdom). We made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui 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. For more information, please see “Business—Exclusive License and Option Agreements.”

Hawkeye Collaboration Agreement

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

Contemporaneously with the execution of the Hawkeye Agreement, we entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye’s common stock at $0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye. See Note 6 to the financial statements for additional information.

Components of Our Results of Operations

Revenue

We have not generated any revenue from the sale of our products, and we do not expect to generate any revenue unless and until we obtain regulatory clearance or approval of, and commercialize, our product candidates.

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 ARQ-151 for plaque psoriasis, the preclinical studies and clinical trials for the continued development of ARQ-151 for atopic dermatitis, ARQ-154 for seborrheic dermatitis and scalp psoriasis, ARQ-252 for hand eczema and vitiligo, and ARQ-255 for alopecia areata.

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

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of ARQ-151, ARQ-154, ARQ-252 and ARQ-255 or any future product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See “Risk Factors” for a discussion of the risks and uncertainties associated with the development of our product candidates.

General and Administrative Expenses

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

Other Income (Expense), Net

Other income (expense), net primarily consists of changes in the fair value of our convertible preferred stock liability and interest income earned on our marketable securities.

Results of Operations

Comparison of the Years 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 primarily 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 costs and manufacturing costs relate to the initiation of the Phase 2b and open label extension studies in ARQ-151 for plaque psoriasis in the second half of 2018 and the initiation of the Phase 2 study in ARQ-151 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 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 associated 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.

Comparison of the Years Ended December 31, 2018 and 2017

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

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands)			
Operating expenses:				
Research and development	$ 17,940	$ 3,411	$ 14,529	426 %
General and administrative	1,795	695	1,100	158 %
Total operating expenses	19,735	4,106	15,629	381 %
Loss from operations	(19,735)	(4,106)	(15,629)	381 %
Other income (expense), net	480	(872)	1,352	(155) %
Net loss	$ (19,255)	$ (4,978)	$ (14,277)	287 %

Research and Development Expenses

	Year Ended December 31,		Change	
	2018	2017	$	%
		(unaudited) (in thousands)		
Direct Costs:				
Preclinical and clinical	$ 8,448	$ 2,166	$ 6,282	290 %
Manufacturing	2,493	271	2,222	820 %
Product milestones	4,400	—	4,400	*
Indirect Costs:				
Compensation and personnel-related	1,566	459	1,107	241 %
Other	1,033	515	518	101 %
Total research and development expense	$ 17,940	$ 3,411	$ 14,529	426 %

Research and development expenses increased by $14.5 million, or 426%, for the year ended December 31, 2018 compared to the year ended December 31, 2017. The increase was due to increases in clinical trial costs of $6.3 million, product milestones of $4.4 million, manufacturing costs of $2.2 million, compensation and personnel-related expenses of $1.1 million, and regulatory and clinical consulting costs of $0.5 million. The increase in clinical trial and manufacturing costs were related to our Phase 2 proof of concept and Phase 2b clinical trials of ARQ-151 for the treatment of plaque psoriasis, which were initiated in 2018. Product milestones consisted of a $4.0 million upfront payment to AstraZeneca, comprised of $1.0 million paid in cash and the issuance of $3.0 million in shares of our Series B convertible preferred stock during 2018, as well as a $0.4 million cash payment made to Hengrui for the option to obtain a license. The increase in compensation and personnel-related expenses, which includes stock compensation, was due to an increase in headcount.

General and Administrative Expenses

General and administrative expenses increased by $1.1 million, or 158%, for the year ended December 31, 2018 compared to the year ended December 31, 2017. The increase was primarily due to an increase of $0.6 million in compensation and personnel-related expenses, which includes stock compensation, due to an increase in headcount. The increase was also driven by increases in professional services of $0.5 million for legal, market research studies and other administrative services.

Other Income (Expense), Net

Other income (expense), net changed by $1.4 million, or 155%, for the year ended December 31, 2018 compared to the year ended December 31, 2017. The change was due to an increase in interest income of $0.4 million from interest earned on the funds received from the issuance of convertible preferred stock in 2018, and a decrease in expense of $0.8 million primarily from the fair value remeasurement of the Series A convertible preferred stock liability and $0.2 million from the fair value remeasurement of the derivative liability related to our promissory notes payable that converted into Series A convertible preferred stock in 2017.

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, 2019 and 2018, we had cash, cash equivalents and marketable securities of $101.3 million and $50.9 million, respectively, and an accumulated deficit of $66.3 million and $24.3 million, respectively. Additionally, we received gross cash proceeds of $183.3 million in connection with our initial public offering in February 2020. We anticipate that operating losses and net cash used in operating activities will increase over the next several years as we further develop ARQ-151, ARQ-154, 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 initial public offering completed in January 2020, and will continue to be dependent upon equity, debt financing or collaborations or other forms of capital at least until we are able to generate positive cash flows from our operations.

Cash Flows

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

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Cash used in operating activities	$ (42,836)	$ (14,085)	$ (3,775)
Cash used in investing activities	(26,325)	(11,532)	—
Cash provided by financing activities	93,103	61,593	7,119
Net increase in cash and cash equivalents	$ 23,942	$ 35,976	$ 3,344

Net Cash Used in Operating Activities

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.

During the year ended December 31, 2017, net cash used in operating activities was $3.8 million and consisted primarily of a net loss of $5.0 million, adjusted by non-cash charges of $0.9 million and a change of $0.3 million in our net operating assets and liabilities. The non-cash charges consisted of a loss from fair value remeasurement of our convertible preferred stock liability of $0.7 million and a loss from fair value measurement of the derivative liability of $0.2 million due to the conversion of our promissory notes payable into Series A convertible preferred stock. The change in our net operating assets and liabilities was primarily due to a net increase of $0.7 million in accounts payable and accrued liabilities due to our overall growth, increased research and development spending and timing of payments. These changes were partially offset by an increase of $0.4 million in prepaid expenses and other current assets for advances made for clinical trial costs.

Net Cash Used in Investing Activities

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, 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.

During the year ended December 31, 2017, net cash provided by financing activities was $7.1 million, primarily comprised of proceeds from the issuance of our Series A convertible preferred stock.

Funding Requirements

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $66.3 million and $24.3 million as of December 31, 2019 and 2018, respectively. We had cash, cash equivalents and marketable securities of $101.3 million and $50.9 million as of December 31, 2019 and 2018, respectively. In February 2020, we received $183.3 million gross cash proceeds from our initial public offering. Based on our current planned operations, we expect that our current cash, cash equivalents and marketable securities will be sufficient to fund our operations through 2021. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

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

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are

unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our currently ongoing Phase 3 studies of ARQ-151 in plaque psoriasis, our planned Phase 2b study of ARQ-151 in atopic dermatitis, our ongoing Phase 2 proof of concept study of ARQ-154 in seborrheic dermatitis, our currently ongoing Phase 2b study of ARQ-154 in scalp psoriasis, our planned Phase 2b study of ARQ-252 in hand eczema, our planned Phase 2a study of ARQ-252 in vitiligo and our formulation and preclinical efforts for ARQ-255 for alopecia areata.
- 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, 2019:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating leases	$ 307	$ 178	$ 129	$ —	$ —
Total obligations	$ 307	$ 178	$ 129	$ —	$ —

We entered into a lease agreement in January 2019 for our headquarters in Westlake Village, California. The term of the lease commenced in March 2019 and terminates in July 2021. The total estimated lease payments for this facility over the term of the lease is approximately $0.5 million.

We are party to license agreements pursuant to which we have in-licensed various intellectual property rights. The license agreements obligate us to make certain milestone payments related to achievement of specified events, as well as royalties in the low single-digits based on sales of licensed products. The table above does not include any milestone or royalty payments to the counterparties to these agreements as the amounts, timing and likelihood of such payments are not known. See Note 6 to our audited financial statements.

We enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

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 the Company does 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 contract research organizations, 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, 2019 and 2018 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 Valuations” 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 $824,000, $151,000, and $27,000 for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, there was $5.6 million of unrecognized compensation expense related to unvested options, which are expected to be recognized over a weighted-average period of approximately 3.64 years. We expect to continue to grant stock options 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 are 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 initial public offering and during the time period of our grants, the fair value of our common stock 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 initial public offering, 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 initial public offering, 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 initial public offering, 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 American Institute of Certified Public Accountants 2013 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 $86,000 and $0.4 million, respectively, as of December 31, 2018.

Income Taxes

As of December 31, 2019, we had net deferred tax assets of $14.9 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 net operating loss, or NOL, tax carryforwards. As of December 31, 2019, we had federal and state NOL carryforwards of $54.6 million and $55.1 million, respectively, available to potentially offset future taxable income. As of December 31, 2019, we also had federal and California research and development tax credit carryforwards of approximately $2.0 million and $0.7 million, respectively, available to potentially offset future federal income taxes. The federal research and development tax carryforwards, if not utilized, will expire beginning in 2037. The California research and development tax credit carryforwards are available indefinitely. Federal and California tax law impose significant restrictions on the utilization of net operating loss 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 net operating loss carryforwards, credit carryforwards, or other tax attributes due to ownership changes.

Recent Accounting Pronouncements

We adopted Accounting Standards Update, or ASU, No. 2016-02, *Leases (Topic 842)*, on January 1, 2019. See Note 2 to our audited financial statements for more information.

Emerging Growth Company Status

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

We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering. 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, 2019, we had cash and cash equivalents of $63.3 million and marketable securities of $37.9 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, 2019.

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

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Item 9B. OTHER INFORMATION

None.

Part III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Key Employees and Directors

The following table provides information regarding our executive officers, key employees and directors as of February 10, 2020:

Name	Age	Position(s)
Executive Officers		
Todd Franklin Watanabe	52	Director, President and Chief Executive Officer
John W. Smither	66	Chief Financial Officer
Howard G. Welgus, M.D.	68	Chief Medical Officer
David W. Osborne, Ph.D.	59	Chief Technical Officer
Kenneth A. Lock	46	Chief Commercial Officer
Patricia A. Turney	53	Senior Vice President, Manufacturing
Key Employees		
David Berk, M.D.	41	Vice President, Clinical Development
Scott L. Burrows	42	Vice President, Finance
Meg Elias	54	Vice President, Clinical Operations
Keith L. Klein, J.D.	56	General Counsel
Charlotte Merritt	57	Vice President, Regulatory Affairs
Lynn Navale	49	Vice President, Biometrics
Frank Pompilio, Pharm.D.	56	Vice President, Medical Affairs
Non-Employee Directors		
Patrick J. Heron(2)	49	Chairman, Director
Alexander G. Asam, Ph.D.(3)	54	Director
Bhaskar Chaudhuri, Ph.D.(1)(2)	65	Director
Daniel J. Estes, Ph.D.(1)(3)	39	Director
Jonathan T. Silverstein, J.D.(2)	52	Director
Ricky Sun, Ph.D.(1)(3)	46	Director
Joseph L. Turner(1)	68	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Governance Committee.

Executive Officers

Todd Franklin Watanabe has served as our President and Chief Executive Officer since April 2017. Prior to joining Arcutis Biotherapeutics, he served as co-founder and Chief Operating Officer of Kanan Therapeutics, Inc., a cardiovascular drug development company from December 2015 to February 2018, and before that, he served as Vice President of Strategy and Corporate Development at Kythera Biopharmaceuticals Inc. from October 2013 to November 2015. Mr. Watanabe was an executive at Amgen, Inc. from 2005 to 2013, where he was involved in the development of Repatha for hyperlipidemia and Aimovig for migraine, and worked on the U.S. marketing of Enbrel in both dermatology and rheumatology. Previously, he was an executive with Eli Lilly and company, and an official in the U.S. Government. He was also a commissioned officer in the U.S. Navy Reserves for 25 years. Mr. Watanabe received his M.A. in National Security Studies, and his B.A. in International Relations, both from Georgetown University. We believe that Mr. Watanabe is qualified to serve on our board of directors because of his experience

with biotechnology companies, including working with and serving in various executive positions in life sciences companies.

John W. Smither has served as our Chief Financial Officer since May 2019. Mr. Smither previously served as Chief Financial Officer for Sienna Biopharmaceuticals, Inc. from January 2016 to March 2017 and again from April 2018 to April 2019. From October 2017 to March 2018, he was interim Chief Financial Officer for Kite Pharma during its integration with Gilead Sciences, Inc., and prior to that, was Chief Financial Officer at Unity Biotechnology, Inc. from January 2016 to July 2017. Earlier, he served as Chief Financial Officer of Kythera Biopharmaceuticals, Inc. from November 2007, until it was acquired by Allergan plc in October 2015. From 1998 to 2007, Mr. Smither held various positions at Amgen Inc., including head of corporate accounting, vice president of finance and administration for Amgen's European Division and head of internal audit. Prior to joining Amgen, he served as audit partner at Ernst & Young LLP, a public accounting firm, and following his time at Ernst & Young served as Chief Financial Officer of several early stage companies. Mr. Smither currently serves on the board of directors of Achaogen, Inc. Previously, Mr. Smither served on the board of directors of Principia Biopharma Inc. He received a B.S. in Business Administration from California State University, Los Angeles. Mr. Smither is a Certified Public Accountant (inactive) and a member of the American Institute of Certified Public Accountants, the California Society of Certified Public Accountants and Financial Executives International.

Howard G. Welgus, M.D. has served as our Chief Medical Officer since April 2017. From February 2016 to June 2018, Dr. Welgus served as the Chief Medical Officer at Verrica Pharmaceuticals Inc. Prior to joining Verrica, Dr. Welgus served as the Chief Medical Officer at Thesan Pharmaceuticals Inc. from September 2012 to November 2016 and served as the Chief Medical Officer at Nycomed US Inc. from May 2009 to November 2010. From 1999 to 2009, he served as the Vice President and head of the Dermatology and Inflammation therapeutic areas in Discovery at Pfizer Inc. in Ann Arbor, MI. Prior to joining the private sector, Dr. Welgus was a faculty member at Washington University for 17 years. Dr. Welgus is a board-certified dermatologist and received a M.D. from Washington University School of Medicine in St. Louis and a B.A. in Biology from Rice University.

David W. Osborne, Ph.D. has served as our Chief Technical Officer since April 2017 and is one of our cofounders. From April 2008 to May 2016, Dr. Osborne held various positions at Tolmar Inc., including Chief Scientific Officer from December 2013 to May 2016. Prior to joining Tolmar, Dr. Osborne served as Vice President of Product Development at Dow Pharmaceutical Sciences, Inc. from September 2003 to March 2008 and at Atrix Laboratories, Inc. through its acquisition of ViroTex Corp. from 1999 to 2003. He started his career as a formulation group leader at The Upjohn Company and as a Group Leader, Skin Care at Calgon Vestal Laboratories, a subsidiary of Merck & Co., Inc. Dr. Osborne received a B.S. in Chemistry from Missouri State University and a Ph.D. in Physical Chemistry from Missouri University of Science and Technology.

Kenneth A. Lock has served as our Chief Commercial Officer since October 2019. Prior to joining Arcutis, he served as the Executive Director of Sales and Marketing at Gilead Sciences, concurrently leading the Inflammation and Pulmonary Hypertension U.S. commercial franchises from December 2013 to August 2019. Prior to Gilead, Mr. Lock was employed at Amgen, Inc. from March 2007 to November 2013, where he was involved in the prelaunch global development of Repatha for hyperlipidemia and also held U.S. brand marketing and sales leadership roles for Enbrel for Rheumatoid Arthritis and Psoriasis. From June 2003 to February 2007 Mr. Lock was at Wyeth Pharmaceuticals where he held various positions including Strategic Planning, International Commercial Operations, and Marketing for Enbrel in both Rheumatology and Dermatology. He started his career in process development and biologics manufacturing at IDEC Pharmaceuticals in 1996. Mr. Lock received both his B.S. in Biochemistry / Cell Biology and B.A. in Psychology from University of California, San Diego and completed his M.B.A at Cornell University.

Patricia A. Turney has served as our Senior Vice President of Manufacturing since November 2019. Prior to joining Arcutis, she was Vice President, External Supply for Amgen, Inc., where she was responsible for the manufacture of over $5B in annual product sales, more than 250 external suppliers, and 55 contract manufacturing sites spanning 10 countries. Previously, she led Amgen's Manufacturing Site Operations in The Netherlands, supplying patients in over 75 countries. Ms. Turney served with Amgen for more than 23 years, and held a wide variety of leadership roles with increasing responsibility within Manufacturing, Engineering, EH&S, R&D, and Quality. She received her B.S. in Mathematics and Engineering from the US Naval Academy, and her M.B.A. from

UCLA's Anderson School of Management. Prior to her career at Amgen, Ms. Turney was a U.S. Naval Aviator and served in the US Navy in various locations around the world.

Key Employees

David Berk, M.D. has served as our Vice President, Clinical Development since January 2019. Prior to joining us, Dr. Berk held various roles of increasing responsibility at Allergan, Inc. from July 2012 to December 2018 and was most recently Executive Director and Section Head for Medical Dermatology. Prior to that, he was in academic practice as an Assistant Professor at Washington University in St. Louis from 2009 to 2012. Dr. Berk is a board-certified Pediatric Dermatologist and completed his Dermatology residency at Washington University in St. Louis and his fellowship training in Pediatric Dermatology at Stanford University. Dr. Berk received a M.D. from Stanford University, and received a A.B. in Molecular Biology from Princeton University.

Scott L. Burrows has served as our Vice President, Finance since May 2019. From March 2018 to May 2019, he was the Head of International Investor Relations for Shire Plc in Zug, Switzerland. Prior to that, Mr. Burrows spent 15 years at Amgen in various Finance roles of increasing responsibility, including Financial Planning & Analysis, Treasury, and Investor Relations. Mr. Burrows started his career as a management consultant with Arthur Andersen in Los Angeles. He received both a B.A. in Business Economics and an M.B.A. from the University of California, Los Angeles and is a Certified Public Accountant (inactive).

Meg Elias has served as our Vice President, Clinical Operations since January 2019. From November 2014 to December 2018, she led the study management group within Clinical Operations at Kite Pharma, and served as the Clinical Operations lead on the pivotal Phase II study which resulted in U.S. and EU market approval of Yescarta. Prior to that, she worked in clinical operations at Amgen from 2003 to 2014 and GlaxoSmithKline from 2000 to 2002. She started her career in clinical nursing, and practiced for 10 years before joining industry. Ms. Elias received a Bachelor of Science in Nursing from Cedar Crest College.

Keith L. Klein, J.D. has served as our General Counsel since November 2019. From January 2016 to May 2017, he was General Counsel for Unity Biotechnology. From October 2006 to October 2015, he was General Counsel for Kythera Biopharmaceuticals, and handled legal matters associated with that firm's IPO and subsequent acquisition by Allergan in October 2015 for $2.1 billion. From 1991 to 2006, he held increasingly senior legal positions at Amgen, Inc., culminating as Senior Associate General Counsel. Prior to that, he was an associate with Cooley Godward LLP and Allen Matkins. He holds a Bachelor of Arts in Economics from University of California, Los Angeles and a Juris Doctorate from University of California, Davis.

Charlotte Merritt has served as our Vice President, Regulatory Affairs since March 2018. In 2014, she founded PharmaReg Consulting, LLC, where she supported smaller pharma and biotech companies with IND-stage development and preparation of NDAs and where she remains the principal. Previously, she spent more than 20 years at Merck & Co. where she contributed to the global registration of numerous therapies and led strategic and organizational transformation initiatives. Ms. Merritt received a B.S. in Biology from Albright College and an M.B.A. from the John M. Olin School of Business at Washington University in St. Louis.

Lynn Navale has served as our Vice President, Biometrics, since September 2019. From July 2014 to September 2019, she was the Vice President of Biometrics at Kite Pharma, where she developed and led the Biometrics function including biostatistics, statistical programming, and data management and served as the Biometrics team leader for the U.S. and EU regulatory approvals of Yescarta. Previously, from 2003 to 2014, she worked at Amgen in roles of increasing responsibility within Clinical Development Biostatistics. She began her career at Baxter BioScience and was the lead statistician for the trial that led to the U.S. regulatory approval of Advate. Ms. Navale has a B.S. in Mathematics from the University of Michigan and an M.S. in Biostatistics from the University of California Los Angeles.

Frank Pompilio, Pharm.D. has served as our Vice President, Medical Affairs, since October 2019. From June 2016 to October 2019, he was Vice President, Medical Affairs at MannKind Corporation. From October 2014 to June 2016, he was Senior Director, Medical Affairs at Kythera Biopharmaceuticals, Inc. Prior to that, Dr. Pompilio was employed at Amgen, Inc. and Bristol-Myers Squibb, where he worked in medical science and scientific affairs functions from July 1996 to September 2014. While at Amgen, he held various leadership roles supporting the

commercialization of Enbrel in both Rheumatology and Dermatology. He started his career as an Assistant Professor at the University of Southern California School of Pharmacy. Dr. Pompilio received a Pharm.D. from USC, a B.S in Pharmacology from the University of California at Santa Barbara, and completed a clinical pharmacy residency at the University of Arizona.

Non-Employee Directors

Patrick J. Heron has served as the Chairman of our board of directors since December 2019, and has been a member of our board of directors since April 2017. Since September 1999, Mr. Heron has been a managing general partner with Frazier Healthcare Partners, where he has been active in company formations and initial investments in various biotechnology companies, including Marcadia Biotech Inc., Calixa Therapeutics, Inc. and VentiRx Pharmaceuticals, Inc. He also led Frazier's involvement in MedPointe Inc. Prior to joining Frazier, Mr. Heron helped develop McKinsey & Company's west coast biotechnology consulting practice. Mr. Heron currently serves on the board of directors of Mirum Pharmaceuticals, Inc. and Iterum Therapeutics plc. He previously served on the boards of directors of the Tobira Therapeutics, Inc. and Collegium Pharmaceuticals, Inc. Mr. Heron received a B.A. in Political Science from the University of North Carolina at Chapel Hill and an M.B.A. from Harvard Business School. We believe that Mr. Heron is qualified to serve on our board of directors because of his investing and operations experiences in the life sciences industry.

Alexander G. Asam, Ph.D. has served as a member of our board of directors since October 2019. Since 2007, Dr. Asam has been an Investment Advisor of HBM Partners, and brings more than 20 years of experience in the life sciences and private equity businesses. He was a former managing director and partner of Deutsche Venture Capital (DVC) / Deutsche Bank from 2001 to 2007 and held various positions at Hoechst AG, Aventis S.A. (now: Sanofi) and LION Bioscience AG, among others, as well as a member of the IPO Core Team (dual listing Germany and USA). Dr. Asam holds an MBA degree from Aston Business School, Birmingham and a MSc and PhD in chemistry from University of Heidelberg. He is a board member of APR Applied Pharma Research and Sublimity Therapeutics, as well as a board observer at Corvidia Therapeutics, Swixx Biopharma, and Vitaeris. We believe that Dr. Asam is qualified to serve on our board of directors because of his extensive experience in the life sciences industry, including as an investor and board member.

Bhaskar Chaudhuri, Ph.D. has served as a member of our board of directors since April 2016 and is one of our co-founders. Since June 2011, he has been the Operating Partner at Frazier Healthcare Ventures. Prior to that time, Dr. Chaudhuri served as President of Valeant Pharmaceuticals International, Inc. (currently Bausch Health) from January 2009 to September 2010. Prior to joining Valeant, Dr. Chaudhuri served for seven years as President and Chief Executive Officer of Dow Pharmaceutical Sciences, Inc. and as a member of its board of directors from 2003 to 2008, at which time Dow was acquired by Valeant. Prior to that, Dr. Chaudhuri served as Executive Vice President of Scientific Affairs at Bertek Pharmaceuticals, Inc., a subsidiary of Mylan N.V., from September 2000 to March 2002. Prior to his position at Bertek, Dr. Chaudhuri served as the General Manager of the Dermatology Division of Mylan from September 1998 to August 2000. Dr. Chaudhuri joined Mylan through the acquisition of Penederm, Inc., where he worked from 1992 to 1998 in a number of senior positions before becoming the Vice President of Research and Development. Dr. Chaudhuri serves on the boards of directors of Teligent, Inc., and previously served on the board of directors of Corium International, Inc. He also serves on the Advisory Board of the Johns Hopkins Berman Institute of Bioethics. Dr. Chaudhuri received a B.S. in Pharmacy and a M.S. in Industrial Pharmacy from Jadavpur University and a Ph.D. in Pharmaceutics from the University of Louisiana. We believe Dr. Chaudhuri is qualified to serve on our board of directors because of his many years of experience in the pharmaceutical industry, including his prior positions in senior executive roles at major pharmaceutical companies.

Daniel J. Estes, Ph.D. has served as a member of our board of directors since April 2017. Since April 2011, Dr. Estes has been a member of the investment team and a partner with Frazier Healthcare Partners, where he focuses on investments in both development-stage and commercial-stage pharmaceutical companies. Prior to joining Frazier Healthcare Partners, Dr. Estes served as a management consultant with McKinsey & Company's healthcare practice between 2008 and 2011. Dr. Estes also served on the board of directors of Sierra Oncology, Inc. from April 2017 until November 2019. Dr. Estes received his Ph.D. in Biomedical Engineering from the University of Michigan and his B.S. in Electrical Engineering from Stanford University. We believe that Dr. Estes is qualified to serve on our board of directors based on his experience in the pharmaceutical and biotechnology industries.

Jonathan T. Silverstein, J.D. has served as a member of our board of directors since August 2018. Mr. Silverstein is currently a Managing Partner and a Co-Head of Global Private Equity at OrbiMed Advisors, a healthcare investment firm, where he has worked since December 1998. Previously, Mr. Silverstein was a director of life sciences in the investment banking department at Sumitomo Bank. Mr. Silverstein currently serves on the board of directors of resTORbio, Inc. and Avedro Inc. Mr. Silverstein has also previously served on the board of directors of Audentes Therapeutics, Inc., Ascendis Pharma A/S, Intercept Pharmaceuticals, Inc., Glaukos Corporation, scPharmaceuticals Inc., Rhythm Pharmaceuticals, Inc. and Sorrento Tech, Inc. (formerly known as Roka BioScience, Inc.). Mr. Silverstein received a B.A. from Denison University and a J.D. and M.B.A. from the University of San Diego. We believe that Mr. Silverstein's strategic development and capital markets experience qualifies him to serve on our board of directors.

Ricky Sun, Ph.D. has served as a member of our board of directors since August 2018. Dr. Sun has been a Partner with Bain Capital Life Sciences since August 2016. From August 2013 to July 2016, he held various positions at Biogen Inc., including Director of Corporate Development and Strategy from January 2015 to July 2016. Prior to Biogen, Dr. Sun served as a Vice President at BlackRock, Inc., as a member of the Fundamental Equity division of BlackRock's Alpha Strategies Group and senior analyst for BlackRock's Fundamental Large Cap Growth equity team, covering the health care sector. Prior to that, he was a senior healthcare analyst at Citadel LLC and Alyeska Investment Group, L.P., in Chicago and worked as a pharmaceuticals equity research analyst on Wall Street, spending time at Lehman Brothers and Morgan Stanley. Dr. Sun received a Ph.D. degree in Chemistry and Chemical Biology from Harvard University, an MBA from New York University Stern School of Business and a B.A. in Chemistry from Berea College. We believe that Dr. Sun's life sciences investment experience qualifies him to serve on our board of directors.

Joseph L. Turner, was elected to become a member of our Board of Directors and Chairman of the Audit Committee in January 2020 upon the effectiveness of our initial public offering. Mr. Turner currently serves on the board of directors and is the chair of the audit committee of Miragen Therapeutics, Inc. Previously, Mr. Turner served as a director and chair of the audit committee of Sophiris Bio Inc., Corcept Therapeutics, Inc., Alexza Pharmaceuticals, Inc. and Kythera Biopharmaceuticals, Inc. Prior to retiring from active employment in 2006, Mr. Turner served as Chief Financial Officer at Myogen, Inc. from 1999 until it was acquired by Gilead Sciences, Inc. in 2006, and previously served as the Chief Financial Officer at Centaur Pharmaceuticals, Inc. and Chief Financial Officer and Vice President, Finance and Administration at Cortech, Inc. Mr. Turner has an M.B.A. from the University of North Carolina at Chapel Hill, an M.A. in molecular biology from the University of Colorado, and a B.A. in chemistry from Swarthmore College. We believe that Mr. Turner possesses specific attributes that qualify him to serve as a member of our board of directors, including his years of experience in the biotech and pharmaceutical industries and his financial sophistication and expertise.

Election of Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.

Board Composition

Our board of directors currently consists of eight members. Seven of our directors are independent within the meaning of the independent director guidelines of the Nasdaq Global Select Market, or Nasdaq.

Our board of directors is divided into three staggered classes of directors. At each annual meeting of stockholders, a class of directors will be subject to re-election for a three-year term. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows:

- the Class I directors are Alexander Asam and Ricky Sun and their terms will expire at the 2021 annual meeting of stockholders;
- the Class II directors are Bhaskar Chaudhuri, Dan Estes and Jonathan Silverstein and their terms will expire at the 2022 annual meeting of stockholders; and

- the Class III directors are Patrick Heron, Joseph Turner and Frank Watanabe and their terms will expire at the 2023 annual meeting of stockholders.

Each director's term continues until the election and qualification of his successor, or his earlier death, resignation or removal. Our restated certificate of incorporation and restated bylaws authorize only our board of directors to fill vacancies on our board of directors. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Director Independence

Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within a specified period following the completion of our initial public offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. We satisfied the audit committee independence requirements of Rule 10A-3 as of the completion of our initial public offering. Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determined that all of our directors, except for Todd Franklin Watanabe, are "independent directors" as defined under the applicable rules and regulations of the Securities and Exchange Commission, or SEC, and the listing requirements and rules of Nasdaq. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain Relationships and Related Party Transactions."

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and governance committee, each of which have the composition and responsibilities described below as of the completion of our initial public offering. Each of the below committees has a written charter approved by our board of directors. Upon completion of our initial public offering, copies of each charter were posted on the investor relations section of our website. Members will serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee is comprised of Joseph Turner, Bhaskar Chaudhuri, Dan Estes, and Ricky Sun, with Joseph Turner as the chairman of our audit committee. The composition of our audit committee meets the requirements for independence under the current Nasdaq and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that Joseph Turner and Bhaskar Chaudhuri are "audit committee financial experts" as defined in Item 407(d)(5)(ii) of Regulation S-K

promulgated under the Securities Act. This designation does not impose on him any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting and hiring our independent registered public accounting firm;
- the qualifications, independence and performance of our registered public accounting firm;
- the preparation of the audit committee report to be included in our annual proxy statement;
- our compliance with legal and regulatory requirements;
- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements; and
- reviewing and approving related-person transactions.

Compensation Committee

Our compensation committee is comprised of Bhaskar Chaudhuri, Patrick Heron, and Jonathan Silverstein, with Bhaskar Chaudhuri as the chairman of our compensation committee. Each member of our compensation committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs;
- evaluating and recommending non-employee director compensation arrangements for determination by our board of directors;
- administering our cash-based and equity-based compensation plans; and
- overseeing our compliance with regulatory requirements associated with the compensation of directors, officers and employees.

Nominating and Governance Committee

Our nominating and governance committee is comprised of Alexander Asam, Dan Estes, and Ricky Sun, with Dan Estes as the chairman of our nominating and governance committee. Each member of our nominating and governance committee meets the requirements for independence under the current Nasdaq listing standards. Our nominating and governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on other corporate governance matters.

Compensation Committee Interlocks and Insider Participation

None of the current members of our compensation committee has at any time been one of our officers or employees. None of our executive officers has served as a member of the board of directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our board of directors or compensation committee during the year ended December 31, 2019. Prior to establishing the compensation committee, our full board of directors made decisions relating to the compensation of our officers.

Code of Business Conduct and Ethics

In connection with our initial public offering, our board of directors adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and other executive and senior officers. The full text of our code of business conduct and ethics is posted on the investor

relations section of our website. The reference to our website address in this Annual Report on Form 10-K does not include or incorporate by reference the information on our website into this Annual Report on Form 10-K. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our website or in public filings to the extent required by the applicable rules.

Non-Employee Director Compensation

The following table presents the total compensation earned by each of our non-employee directors in the year ended December 31, 2019. Our President and Chief Executive Officer, Mr. Watanabe, receives no compensation for his service as a director. Other than as described below, none of our non-employee directors received any fees or reimbursement of any expenses (other than customary expenses in connection with the attendance of meetings of our board of directors) or any equity or non-equity awards in the year ended December 31, 2019.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)(2)	Option Awards ($)(1)(2)	Total ($)
Bhaskar Chaudhuri, Ph.D.	183,333 (3)	—	109,306	292,639
Daniel Estes, Ph.D.	—	—	—	—
Patrick J. Heron	—	—	—	—
Jonathan T. Silverstein, J.D.	—	—	—	—
Ricky Sun, Ph.D.	—	—	—	—
Charlie Stiefel, J.D(4)	—	78,705	—	78,705

(1) The amounts reported in the Stock Awards and Option Awards column represent the grant date fair value of the restricted stock and stock options granted to the directors during the year ended December 31, 2019 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the restricted stock and stock options reported in the Stock Awards and Option Awards column are set forth in Note 9 to the audited financial statements. Note that the amounts reported in this column reflect the accounting cost for these restricted stock and stock options, and do not correspond to the actual economic value that may be received by the named executive officers from the restricted stock and options.

(2) The following table sets forth the aggregate number of shares of our common stock subject to outstanding equity awards held by our non-employee directors as of December 31, 2019:

Director name	Number of unvested shares underlying stock awards held as of December 31, 2019	Number of vested shares underlying stock awards held as of December 31, 2019(A)	Number of shares underlying options held as of December 31, 2019(A)
Bhaskar Chaudhuri, Ph.D.	168,771 (B)	101,263	99,965 (C)
Daniel Estes, Ph.D.	—	—	—
Patrick J. Heron	—	—	—
Jonathan T. Silverstein, J.D.	—	—	—
Ricky Sun, Ph.D.	—	—	—
Charlie Stiefel, J.D.	—	13,245	—

(A) All of the outstanding awards were granted under our 2017 Plan.
(B) This amount reflects the unvested portion of stock awards vesting monthly over a four year period from June 11, 2018, issued upon the early exercise of an option award. 100% of the unvested portion of stock awards will vest upon a change of control.
(C) The stock option vests monthly over a four year period beginning upon the achievement of certain company milestones, subject to the holder's continuous provision of services to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to the unvested shares, subject to our right of repurchase. 100% of the options will vest upon a change of control.

(3) Pursuant to an agreement dated August 16, 2016 between us and Dr. Chaudhuri, we paid Dr. Chaudhuri $200,000 to provide services to us as Chair of our board of directors. This agreement was terminated in December 2019 upon his resignation as chairman of our board of directors.

(4) Mr. Stiefel resigned from our board of directors on September 5, 2019.

Prior to our initial public offering, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service on our board of directors or committees of our board of directors. In August 2016, we entered into an agreement, or the Chaudhuri Agreement, with Bhaskar Chaudhuri to provide services to us as Chair of our board of directors. Pursuant to the Chaudhuri Agreement, we paid Dr. Chaudhuri an annualized fee of $200,000 for his services as a director and chairman of our board of directors through December 2019. The Chaudhuri Agreement was terminated in December 2019 upon Dr. Chaudhuri's resignation as chairman of our board of directors.

In January 2020, our board of directors approved compensation for our non-employee directors, to be effective in connection with the consummation of our initial public offering. Our non-employee directors will receive annual cash compensation of $37,500 for service on the board, and additional cash compensation for the chairperson and committee members as set forth below. All cash payments will be made quarterly in arrears, and pro-rated for any partial quarters of service.

- Chair of the Board: $30,000
- Audit Committee Chair: $15,000
- Audit Committee Member (Non-Chair): $7,500
- Compensation Committee Chair: $10,000
- Compensation Committee Member (Non-Chair): $5,000
- Nominating and Corporate Governance Committee Chair: $8,000
- Nominating and Corporate Governance Committee Member (Non-Chair): $4,000

In addition, each non-employee director who is elected or appointed to our board of directors will be granted an option to purchase 37,500 shares of our common stock upon the director's initial appointment to our board of directors, referred to as the Initial Grant. The Initial Grant will vest in 3 equal installments on each anniversary of the date of grant, such that the Initial Grant will become fully vested and exercisable on the third anniversary of the date of grant, subject to the director's continued service on each applicable vesting date. If the non-employee director's service ends on the date of vesting, then the vesting will be deemed to have occurred.

Effective upon our initial public offering in January 2020, Mr. Turner received an Initial Grant.

Each non-employee director who is serving on our board of directors immediately prior to, and will continue to serve on the Board following, our annual meeting of stockholders, will be granted an option to purchase 18,750 shares of our common stock on the date of such annual meeting of stockholders, referred to as the Annual Grant. Each Annual Grant will vest on the earlier of (a) the next annual meeting of the Company's stockholders, or (b) the one-year anniversary of the grant date of the Annual Grant, subject to the director's continued service on the applicable vesting date. If the non-employee director's service ends on the date of vesting, then the vesting will be deemed to have occurred.

In certain instances, the cash compensation payments and/or option grants have either been declined by the non-employee directors or remitted to their associated investor fund.

The non-employee director Initial Grants and Annual Grants will be made pursuant to the 2020 Plan, and will be subject to the terms and conditions set forth in the applicable stock option agreements under such plan. The Initial Grant and the Annual Grant will accelerate in full upon the consummation of a Corporate Transaction, as defined under the 2020 Plan.

Item 11. EXECUTIVE COMPENSATION

The following tables and accompanying narrative disclosure set forth information about the compensation earned by our named executive officers during the year ended December 31, 2019. Our named executive officers, who are our principal executive officer and the two most highly-compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2019, were:

- Todd Franklin Watanabe, President and Chief Executive Officer;
- Kenneth A. Lock, Chief Commercial Officer; and
- Patricia A. Turney, Senior Vice President, Manufacturing.

Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was awarded to and earned by our named executive officers during the year ended December 31, 2019.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)		Non-equity Incentive Plan Compensation ($)(2)	Total($)
Todd Franklin Watanabe	2019	390,000	580,546	(3)	169,750	1,140,296
President and Chief Executive Officer	2018	327,083	180,992	(4)	126,000	634,075
Kenneth A. Lock	2019	66,932	674,797	(5)	24,346	766,075
Chief Commercial Officer						
Patricia A. Turney	2019	34,375	666,834	(6)	12,504	713,713
Senior Vice President, Manufacturing						

(1) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to the named executive officers during the year ended December 31, 2019 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option Awards column are set forth in Note 9 to the audited financial statements. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the named executive officers from the options.

(2) For additional information regarding the non-equity incentive plan compensation, see "—Non-equity Incentive Plan Awards."

(3) Consists of 24,991 options which vest monthly over a four year period beginning on November 20, 2019 and 435,946 options which vest monthly over a four year period after completion of certain company milestones, subject to the optionee's continuous provision of service to us through each such date. The option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase. In addition to the foregoing vesting arrangements, the option is subject to acceleration upon certain events as described in the section titled "—Employee Offer Letters—Potential Payments upon Termination or Change in Control."

(4) The option vests monthly over a four year period beginning March 1, 2018, subject to the optionee's continuous provision of services to us through each such date. The option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase. In addition to the foregoing vesting arrangements, the option is subject to acceleration upon certain events as described in the section titled "—Employee Offer Letters—Potential Payments upon Termination or Change in Control."

(5) The option vests 1/4 after one year and monthly over a four year period beginning October 14, 2019, subject to the optionee's continuous provision of services to us through each such date. The option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase. In addition to the foregoing vesting arrangements, the option is subject to acceleration upon certain events as described in the section titled "—Employee Offer Letters—Potential Payments upon Termination or Change in Control."

(6) The option vests 1/4 after one year and monthly over a four year period beginning November 14, 2019, subject to the optionee's continuous provision of services to us through each such date. The option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase. In addition to the foregoing vesting arrangements, the option is subject to acceleration upon certain events as described in the section titled "—Employee Offer Letters—Potential Payments upon Termination or Change in Control."

Non-equity Incentive Plan Awards

Annual bonuses for our executive officers are based on the achievement of corporate and, for all of the executive officers other than our Chief Executive Officer, individual performance objectives. For the 2019 bonuses to be paid by March 2020, the corporate performance objectives included advancing the ARQ-151, ARQ-154 and ARQ-252 programs, providing clinical supply to support planned studies, and the completion of a target level of financing. In February 2020, our compensation committee determined to award bonuses for 2019 performance equal to 121% of target. For the 2018 bonuses paid in March 2019, the corporate performance objectives included the delivery of a development candidate, the completion of a target level of financing, and the establishment of development infrastructure capable of supporting advancement of the development candidates into the clinic. In March 2019, based on the achievement of these corporate performance objectives and satisfaction of individual performance goals, our compensation committee determined to award bonuses equal for 2018 performance to 100% of target.

Outstanding Equity Awards at 2019 Fiscal Year-End Table

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2019. All awards were granted under our 2017 Plan.

	Option Awards				Stock Awards		
Name	Number of Securities Underlying Unexercised Options Exercisable (#) (1)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#) (1)		Market Value of Shares or Units of Stock That Have Not Vested ($) (2)
Todd Franklin Watanabe	—	—	—	—	121,831	(3)	2,071,127
	—	—	—	—	109,770	(4)	1,866,090
	435,946 (5)	—	1.68	3/13/2029	—		—
	24,991 (6)	—	6.52	11/20/2029	—		—
Kenneth A. Lock	159,943 (7)	—	6.52	10/28/2029	—		—
Patricia A. Turney	159,943 (8)	—	6.52	11/20/2029	—		—

(1) Each award is subject to the acceleration of vesting provisions in each named executive officers' severance & change in control agreement, as set forth below in the section titled "—Employee Offer Letters.".

(2) Since we had not yet completed our initial public offering and no public market offering existed for our stock as of December 31, 2019, the market value was computed using $17.00, which is our initial public offering price.

(3) The restricted stock was acquired through the early exercise of a stock option at an exercise price of $0.36 per share. The restricted stock vests monthly over a four year period beginning November 8, 2016, subject to the holder's continuous provision of services to us on each vesting date.

(4) The restricted stock was acquired through the early exercise of a stock option at an exercise price of $0.36 per share. The restricted stock vests monthly over a four year period beginning March 1, 2018, subject to the holder's continuous provision of services to us on each vesting date.

(5) The stock option vests monthly over a four year period beginning upon the achievement of certain company milestones, subject to the holder's continuous provision of services to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase.

(6) The stock option vests monthly over a four year period beginning November 20, 2019, subject to the holder's continuous provision of services to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase.

(7) The stock option vests 1/4 on the one year anniversary and monthly thereafter over a four year period beginning October 14, 2019, subject to the holder's continuous provision of services to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase.

(8) The stock option vests 1/4 on the one year anniversary and monthly thereafter over a four year period beginning November 14, 2019, subject to the holder's continuous provision of services to us on each vesting date. This stock option contains an early-exercise provision and is exercisable as to unvested shares, subject to our right of repurchase.

Employee Offer Letters

Employment Arrangements with our Named Executive Officers.

Each of our named executive officers has entered into an offer letter that provides for at-will employment and generally includes the named executive officer's initial base salary, an indication of eligibility for an annual cash incentive award opportunity, equity awards and employee benefit plan participation. In addition, each of our named executive officers has executed a form of our standard confidential information and invention assignment agreement. Any potential payments and benefits due upon a termination of employment in connection with a change in control of us are described below in "—Potential Payments upon Termination or Change in Control."

Potential Payments upon Termination or Change in Control

We have entered into severance & change in control agreements, or Severance & Change in Control Agreements, with each of our named executive officers.

These agreements provide for each of these named executive officers to receive the benefits described below upon either a termination by us of the named executive officer's employment without "cause" or a voluntarily resignation by the named executive officer from his or her employment for "good reason" (each, as defined in the Severance & Change in Control Agreement) either outside of a "change in control" (as defined in the Severance & Change in Control Agreements) or in connection with a change in control. We refer to either of these terminations as a "qualifying termination." These benefits are contingent upon the named executive officer executing a customary release of claims. The benefits under the Severance & Change in Control Agreements will supersede all other agreements and understandings between us and each of the named executive officers with respect to severance and vesting acceleration, if any.

In the event of a qualifying termination that occurs during the period from three months before a change in control to 18 months after a change in control (the "change in control period"), each of these named executive officers are entitled to: (1) payment equal to 12 months of base salary or, in the case of Mr. Watanabe, 18 months of base salary, (2) payment equal to 1.0 times, or, in the case of Mr. Watanabe, 1.5 times, the named executive officer's annual bonus for the then-current fiscal year, based on 100% of target performance, (3) continued coverage under our group-healthcare plans for a period ending on the earlier of (x) 12 months or, in the case of Mr. Watanabe, 18 months, following the termination date and (y) the date that the named executive officer and his or her covered dependents become eligible for coverage under another employer's plans and (4) acceleration of 100% of the vesting of each then-outstanding and unvested equity award, provided, that awards subject to the satisfaction of performance criteria may provide for alternative treatment and, absent any such treatment in such grant agreement, the vesting acceleration shall be deemed to have been met based on the achievement of the award at the greater of "at target" or, if determinable, actual performance. The vesting of any outstanding equity award that is not assumed by a successor company following a change in control of us will automatically accelerate in full without regard to the named executive officer's termination of service.

In the event of a qualifying termination that occurs outside of the change in control period, each of these named executive officers are entitled to (1) payment equal to 9 months of base salary or, in the case of Mr. Watanabe, 12 months of base salary and (2) continued coverage under our group-healthcare plans for a period ending on the earlier of (x) 9 months or, in the case of Mr. Watanabe, 12 months, following the termination date and (y) the date that the named executive officer and his or her covered dependents become eligible for coverage under another employer's plans.

Employee Benefit Plans

We believe that our ability to grant equity-based awards is a valuable compensation tool that enables us to attract, retain, and motivate our employees, consultants, and directors by aligning their financial interests with those of our stockholders. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to this Annual Report on Form 10-K.

2017 Equity Incentive Plan

We maintain our 2017 Equity Incentive Plan, as amended, or the 2017 Plan. The purposes of the 2017 Plan are to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to employees, directors and consultants and to promote the success of our business. The material terms of the 2017 Plan are summarized below:

Share Reserve. Subject to adjustment as provided in the 2017 Plan, the maximum number of shares of common stock which may be issued under the 2017 Plan is 5,249,615 shares, which includes 1,411,404 shares authorized to be available for grant in connection with the issuance of our Series C convertible preferred stock in October 2019. 1,550,150 shares remained available for grant under the 2017 Plan as of December 31, 2019. As of December 30, 2019, 1,169,750 options to purchase shares had been exercised and options to purchase 2,516,470 shares remained outstanding, with a weighted average exercise price of $3.47 per share.

Administration. Our 2017 Plan is administered by our board of directors or a committee appointed by our board of directors. Subject to the terms of the 2017 Plan, our board of directors has the authority to, among other things, select the persons to whom awards will be granted, construe and interpret our 2017 Plan as well as to prescribe, amend and rescind rules and regulations relating to the 2017 Plan and awards granted thereunder.

Eligibility. Pursuant to the 2017 Plan, we may grant incentive stock options only to our employees (including officers and directors who are also employees). We may grant non-statutory stock options to our employees (including officers and directors who are also employees), non-employee directors and consultants.

Options. The 2017 Plan provides for the grant of both (i) incentive stock options, which are intended to qualify for tax treatment as set forth under Section 422 of the Internal Revenue Code, as amended, or the Code, and (ii) non-statutory stock options to purchase shares of our common stock, each at a stated exercise price. The exercise price of each stock option must be at least equal to the fair market value of our common stock on the date of grant, unless expressly determined by the board of directors or committee on the date of the grant. However, the exercise price of any incentive stock option granted to an individual who owns more than ten percent of the total combined voting power of all classes of our capital stock must be at least equal to 110% of the fair market value of our common stock on the date of grant.

The maximum permitted term of options granted under our 2017 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual who owns more than ten percent of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Restricted Stock, Restricted Stock Units and Stock Appreciation Rights. In addition, the 2017 Plan allows for the grant of restricted stock awards, restricted stock units and stock appreciation rights, with terms as generally determined by the administrator (in accordance with the 2017 Plan) and to be set forth in an award agreement. In January 2020, we granted 13,245 shares of restricted stock. We have not granted any other shares of restricted stock (other than in connection with the “early exercise” of stock options”), any restricted stock units or any stock appreciation rights under the 2017 Plan.

Limited Transferability. Unless otherwise determined by our board of directors, awards under the 2017 Plan generally may not be transferred or assigned in any manner other than by will or the laws of descent and distribution, or certain gifts to family members.

Change of Control. In the event that we are subject to an “acquisition” or “other combination” (as defined in the 2017 Plan and generally meaning, collectively, a merger, a sale or transfer of more than 50% of the voting power of all of our outstanding securities, or a sale of all or substantially all of our assets), the 2017 Plan provides that awards will be subject to the agreement evidencing such acquisition or other combination, which agreement need not treat all awards in a similar manner. Such agreement may, without the participant’s consent, provide for the continuation of outstanding awards, the assumption or substitution of awards, the acceleration of vesting of awards, the settlement of awards (whether or not vested) in cash, securities or other consideration, or the cancellation of such awards for no consideration.

Adjustments. In the event of a stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification, or other change in our capital structure affecting the shares without consideration, the number and class of shares that may be delivered under 2017 Plan (including any share limits related thereto) and/or the number, class and price of shares covered by each outstanding award will (to the extent appropriate) be appropriately adjusted (subject to required action by the board), in order to prevent diminution or enlargement of

benefits or potential benefits intended to be made available under the 2017 Plan or otherwise as required by applicable law.

Exchange, repricing and buyout of awards. The administrator may, with the consent of the respective participants, issue new awards in exchange for the surrender and cancellation of any or all outstanding awards. The administrator may also reduce the exercise price of options or stock appreciation rights or buy an award previously granted with payment in cash, shares or other consideration, in each case, subject to the terms of the 2017 Plan.

Amendment/termination. The board of directors may amend or terminate the 2017 Plan at any time and may terminate any and all outstanding options, stock appreciation rights or restricted stock units upon a dissolution or liquidation of us, provided that certain amendments will require shareholder approval. We ceased issuing awards under the 2017 Plan upon the effective date of our 2020 Equity Incentive Plan (described below). Any outstanding awards granted under the 2017 Plan will remain outstanding, subject to the terms of our 2017 Plan and applicable award agreements, until such awards are exercised or until they terminate or expire by their terms.

2020 Equity Incentive Plan

We have adopted our 2020 Equity Incentive Plan, or the 2020 Plan, that became effective upon our initial public offering, and will serve as the successor to our 2017 Plan. Our 2020 Plan provides for the award of stock options, restricted stock awards, or RSAs, stock appreciation rights, or SARs, restricted stock units, or RSUs, performance awards and stock bonus awards.

Share Reserve. We have initially reserved 2,134,000 shares of our common stock, plus any reserved shares not issued or subject to outstanding grants under the 2017 Plan on the effective date of the 2020 Plan, for issuance pursuant to awards granted under our 2020 Plan. The number of shares reserved for issuance under our 2020 Plan will increase automatically on January 1 of each of the first ten calendar years during the term of the 2020 Plan by the number of shares equal to the lesser of 4% of the aggregate number of outstanding shares of all classes of our common stock as of the immediately preceding December 31, or a number as may be determined by our board of directors.

In addition, the following shares will again be available for issuance pursuant to awards granted under our 2020 Plan:

- shares subject to options or SARs granted under our 2020 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;
- shares subject to awards granted under our 2020 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under our 2020 Plan that otherwise terminate without such shares being issued;
- shares subject to awards granted under our 2020 Plan that are surrendered, cancelled or exchanged for cash or a different award (or combination thereof);
- shares used to pay the exercise price, or withheld to satisfy the tax withholding obligations related to an award, granted under our 2020 Plan;
- shares that are subject to stock options or other awards granted under the 2017 Plan that cease to be subject to such stock options or other awards by forfeiture or otherwise, after the termination of the 2017 Plan;
- shares issued under the 2017 Plan pursuant to the exercise of stock options that are forfeited or are repurchased by us at the original issue price, after the termination of the 2017 Plan; and
- shares that are subject to stock options or other awards under the 2017 Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

Administration. Our 2020 Plan will be administered by our compensation committee, or by our board of directors acting in place of our compensation committee. Subject to the terms and conditions of the 2020 Plan, the compensation committee will have the authority, among other things, to select the persons to whom awards may be granted, construe and interpret our 2020 Plan as well as to determine the terms of such awards and prescribe, amend and rescind the rules and regulations relating to the plan or any award granted thereunder, including for

purposes of compliance with any applicable laws and regulations of any relevant jurisdictions outside the United States. The 2020 Plan provides that the board or compensation committee may delegate its authority, including the authority to grant awards, to a sub-committee or to one or more executive officers to the extent permitted by applicable law, provided that awards granted to non-employee directors may only be determined by our board of directors.

Eligibility. Our 2020 Plan provides for the grant of awards to our employees, directors, consultants, independent contractors and advisors. No non-employee director may receive awards under our 2020 Plan that, when combined with cash compensation received for services as a non-employee director, exceed $750,000 in a calendar year or $1,000,000 in the calendar year of his or her initial services as a non-employee director with us.

Options. The 2020 Plan provides for the grant of both incentive stock options intended to qualify under Section 422 of the Code, and non-statutory stock options to purchase shares of our common stock at a stated exercise price. Incentive stock options may only be granted to employees, including officers and directors who are also employees. The exercise price of stock options granted under the 2020 Plan must be at least equal to the fair market value of our common stock on the date of grant. Incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock must have an exercise price of at least 110% the fair market value of our common stock on the date of grant. Subject to stock splits, dividends, recapitalizations or similar events, no more than 11,000,000 shares may be issued pursuant to the exercise of incentive stock options granted under the 2020 Plan.

Options may vest based on service or achievement of performance conditions. Our compensation committee may provide for options to be exercised only as they vest or to be immediately exercisable, with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. The maximum term of options granted under our 2020 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Restricted Stock Awards. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the compensation committee. Holders of RSAs, unlike holders of options, will have the right to vote and any dividends or stock distributions paid pursuant to RSAs will be accrued and paid when the restrictions on such shares lapse. Unless otherwise determined by the compensation committee at the time of award, vesting will cease on the date the participant no longer provides services to us and unvested shares may be forfeited to or repurchased by us.

Stock Appreciation Rights. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by our compensation committee), to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The exercise price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may vest based on service or achievement of performance conditions, and may not have a term that is longer than ten years from the date of grant.

Restricted Stock Units. RSUs represent the right to receive shares of our common stock at a specified date in the future, and may be subject to vesting based on service or achievement of performance conditions. Payment of earned RSUs will be made as soon as practicable on a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both. No RSU may have a term that is longer than ten years from the date of grant.

Performance Awards. Performance awards granted pursuant to the 2020 Plan may be in the form of a cash bonus, or an award of performance shares or performance units denominated in shares of our common stock that may be settled in cash, property or by issuance of those shares subject to the satisfaction or achievement of specified performance conditions.

Stock Bonus Awards. A stock bonus award provides for payment in the form of cash, shares of our common stock or a combination thereof, based on the fair market value of shares subject to such award as determined by our compensation committee. The awards may be granted as consideration for services already rendered, or at the discretion of the compensation committee, may be subject to vesting restrictions based on continued service or performance conditions.

Change of Control. In the event of a corporate transaction (as defined in the 2020 Plan), any or all outstanding awards may be (a) continued by the company, if the company is the successor entity; or (b) assumed or substituted by the successor corporation, or a parent or subsidiary of the successor corporation, for substantially equivalent awards (including, but not limited to, a payment in cash or the right to acquire the same consideration paid to the stockholders of the company pursuant to the corporate transaction), in each case after taking into account appropriate adjustments for the number and kind of shares and exercise prices. The successor corporation may also issue, as replacement of outstanding shares of the company held by a participant, substantially similar shares or other property subject to repurchase restrictions no less favorable to the participant. In the event such successor corporation refuses to assume, substitute or replace any award, then each such award shall become fully vested and, as applicable, exercisable and any rights of repurchase or forfeiture restrictions thereon shall lapse, immediately prior to the consummation of the corporation transaction. Performance awards not assumed pursuant to the foregoing shall be deemed earned and vested at 100% of target level, unless otherwise indicated pursuant to the terms and conditions of the applicable award agreement. If an award vests in lieu of assumption or substitution in connection with a corporate transaction as provided above, the board or committee will notify the holder of such award in writing or electronically that such award will be exercisable for a period of time determined by the board or committee in its sole discretion, and such award will terminate upon the expiration of such period without consideration. Any determinations by the board or committee need not treat all outstanding awards in an identical manner, and shall be final and binding on each applicable participant.

The vesting of all awards granted to our non-employee directors shall accelerate in full in the event of a corporate transaction.

Adjustment. In the event of a change in the number of outstanding shares of our common stock without consideration by reason of a stock dividend, extraordinary dividend or distribution (whether in cash, shares or other property, other than a regular cash dividend), recapitalization, stock split, reverse stock split, subdivision, combination, consolidation reclassification, spin-off or similar change in our capital structure, appropriate proportional adjustments will be made to the number and class of shares reserved for issuance under our 2020 Plan; the exercise prices, number and class of shares subject to outstanding options or SARs; the number and class of shares subject to other outstanding awards; and any applicable maximum award limits with respect to incentive stock options.

Clawback; Transferability. All awards will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by our board of directors or required by law during the term of service of the award holder, to the extent set forth in such policy or applicable agreement. Except in limited circumstances, awards granted under our 2020 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

Amendment and Termination. Our board of directors may amend our 2020 Plan at any time, subject to stockholder approval as may be required. Our 2020 Plan will terminate ten years from the date our board of directors adopts the plan, unless it is terminated earlier by our board of directors. No termination or amendment of the 2020 Plan may adversely affect any then-outstanding award without the consent of the affected participant, except as is necessary to comply with applicable laws.

2020 Employee Stock Purchase Plan

We have adopted a 2020 Employee Stock Purchase Plan, or ESPP, that became effective upon our initial public offering in order to enable eligible employees to purchase shares of our common stock with accumulated payroll deductions. Our ESPP is intended to qualify under Section 423 of the Code.

Shares Available. We have initially reserved 351,000 shares of our common stock for sale under our ESPP. The aggregate number of shares reserved for sale under our ESPP will increase automatically on January 1st of each of the first ten calendar years after the first offering date by the number of shares equal to the lesser of 1.0% of the total outstanding shares of our common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by our board of directors in any particular year. The aggregate number of shares issued over the term of our ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed 5,265,000 shares of our common stock.

Administration. Our ESPP is administered by our compensation committee, or by our board of directors acting in place of our compensation committee, subject to the terms and conditions of the ESPP. Among other

things, the compensation committee has the authority to determine eligibility for participation in the ESPP, designate separate offerings under the plan, and construe, interpret and apply the terms of the plan.

Eligibility. Employees eligible to participate in any offering pursuant to the ESPP generally include any employee that is employed by us or certain of our designated subsidiaries at the beginning of the offering period. However, our compensation committee may determine that employees who are customarily employed for 20 hours or less per week or for five months or less in a calendar year, certain "highly compensated" employees or employees resident in a foreign jurisdiction whose participation is either prohibited under local law, or where compliance with local law would violate Section 423 of the Code, may not be eligible to participate in the ESPP. In addition, any employee who owns (or is deemed to own as a result of attribution) 5% or more of the total combined voting power or value of all classes of our capital stock, or the capital stock of one of our qualifying subsidiaries, or who will own such amount as a result of participation in the ESPP, will not be eligible to participate in the ESPP. The compensation committee may impose additional restrictions on eligibility from time to time.

Offerings. Under our ESPP, eligible employees will be offered the option to purchase shares of our common stock at a discount over a series of offering periods. Each offering period may itself consist of one or more purchase periods. No offering period may be longer than 27 months.

Participation. Participating employees will be able to purchase the offered shares of our common stock by accumulating funds through payroll deductions. Participants may select a rate of payroll deduction between 1% and 15% of their eligible compensation. However, a participant may not subscribe for more than $25,000 in fair market value of shares of our common stock (determined as of the date the offering period commences) in any calendar year in which the offering is in effect. In addition, no participant will be permitted to purchase more than 4,000 shares during any one purchase period or such greater or lesser amount determined by our compensation committee, in its discretion.

The purchase price for shares of our common stock purchased under the ESPP will be 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of each purchase period in the applicable offering period.

Once an employee becomes a participant in an offering period, the participant will be automatically enrolled in each subsequent offering period at the same contribution level. A participant may reduce his or her contribution in accordance with procedures set forth by the compensation committee and may withdraw from participation in the ESPP at any time prior the end of an offering period, or such other time as may be specified by the compensation committee. Upon withdrawal, the accumulated payroll deductions will be returned to the participant without interest.

Adjustments upon Recapitalization. If the number of outstanding shares of our common stock is changed by stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or similar change in our capital structure without consideration, then our compensation committee will proportionately adjust the number and class of common stock that is available under the ESPP, the purchase price and number of shares any participant has elected to purchase as well as the maximum number of shares which may be purchased by participants.

Change of Control. If we experience a change of control transaction, outstanding rights to purchase shares will be assumed or an equivalent option substituted by the successor corporation. In the event that the successor corporation refuses to assume or substitute for the purchase right, any offering period that commenced prior to the closing of the proposed change of control transaction will be shortened and terminated on a new purchase date. The new purchase date will occur on or prior to the closing of the proposed change of control transaction, and our ESPP will then terminate on the closing of the proposed change of control.

Transferability. A participant may not assign, transfer, pledge or otherwise dispose of payroll deductions credited to his or her account, or any rights with regard to an election to purchase shares pursuant to the ESPP other than by will or the laws of descent or distribution.

Amendment; Termination. The compensation committee may amend, suspend or terminate the ESPP at any time without stockholder consent, except as required by law. Our ESPP will continue until the earlier to occur of (a) termination of the ESPP by the Board, (b) issuance of all of the shares reserved for issuance under the ESPP, or (c) the tenth anniversary of the first purchase date under the ESPP.

401(k) Plan

We sponsor a retirement savings plan that is intended to qualify for favorable tax treatment under Section 401(a) of the Code, and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. Participants may make pre-tax and certain after-tax (Roth) salary deferral contributions to the plan from their eligible earnings up to the statutorily prescribed annual limit under the Code. Participants who are 50 years of age or older may contribute additional amounts based on the statutory limits for catch-up contributions. Participant contributions are held in trust as required by law. No minimum benefit is provided under the plan. An employee's interest in his or her salary deferral contributions is 100% vested when contributed. As of December 31, 2019, we do not match contributions, however we are implementing a match in 2020.

Other Benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

Limitations on Liability and Indemnification Matters

Our restated certificate of incorporation that became effective in connection with the completion of our initial public offering contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our restated certificate of incorporation and our restated bylaws require us to indemnify our directors and officers to the maximum extent not prohibited by the DGCL and allow us to indemnify other employees and agents as set forth in the DGCL.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors, officers and certain of our key employees, in addition to the indemnification provided for in our restated certificate of incorporation and restated bylaws. These agreements, among other things, require us to indemnify our directors, officers and key employees for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to us or any of our subsidiaries or any other company or enterprise to which these individuals provide services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted.

We believe that these indemnification provisions and agreements are necessary to attract and retain qualified directors, officers and key employees. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our restated certificate of incorporation and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

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

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of our common stock at February 10, 2020:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who beneficially owned more than 5% of our outstanding shares of common stock.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Beneficial ownership is based on 38,088,959 shares of common stock outstanding as of February 10, 2020, including 702,750 shares of unvested common stock subject to repurchase, including the conversion of all outstanding shares of our convertible preferred stock into 24,385,388 shares of our common stock.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of February 10, 2020. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Arcutis Biotherapeutics, Inc., 2945 Townsgate Road, Suite 110, Westlake Village, CA 91361.

	Number of Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percent**
Directors and Named Executive Officers:		
Todd Franklin Watanabe(1)	1,150,021	3.0 %
Kenneth A. Lock(2)	159,943	*
David W. Osborne, Ph.D.(3)	460,211	1.2
John W. Smither(4)	289,896	*
Patricia A. Turney(5)	159,943	*
Howard G. Welgus, M.D.(6)	352,591	*
Bhaskar Chaudhuri, Ph.D.(7)	1,051,337	2.8
Daniel J. Estes, Ph.D.(8)	—	—
Patrick J. Heron(9)	10,542,790	27.7
Jonathan T. Silverstein, J.D.(10)	4,673,854	12.3
Ricky Sun, Ph.D.(11)	—	—
Alexander G. Asam, Ph.D.(12)	—	—
Joseph L. Turner	—	—
All executive officers and directors as a group (12 persons)(13)	17,522,169	47.8
5% or Greater Stockholders:		
Bain Capital Life Sciences Entities(14)	3,979,292	10.4
Frazier Life Sciences VIII, L.P.(15)	10,542,790	27.7
OrbiMed Private Investments VII, LP(16)	4,673,850	12.3

* Represents beneficial ownership of less than one percent.

(1) Consists of (i) 478,447 shares of our common stock held of record by Todd Franklin Watanabe, (ii) 124,956 shares of our common stock held of record by The Watanabe 2016 Irrevocable Trust, (iii) 49,981 shares of our common stock held of record by Watanabe Ventures, LLC, (iv) 17,850 shares of our common stock held of record by The Anderson Prest Watanabe Irrevocable Trust dated 12 December 2006, (v) 17,850 shares of our common stock held of record by The John Franklin Watanabe Trust dated 25 July 2001, and (vi) 460,937 shares of our common stock subject to options that are exercisable within 60 days of February 10, 2020, 458,855 of which shares are unvested, but early exercisable.

(2) Consists of 159,943 shares of our common stock subject to options that are exercisable within 60 days of February 10, 2020, of which all are unvested, but early exercisable.

(3) Consists of (i) 270,279 shares of our common stock held of record by David W. Osborne, (ii) 62,478 shares of our common stock held of record by The Osborne Irrevocable Trust FBO John Osborne, dated July 1, 2019, (iii) 62,478 shares of our common stock held of record by The Osborne Irrevocable Trust FBO Sharon Osborne, dated July 1, 2019, and (iv) 64,976 shares of our common stock subject to options that are exercisable within 60 days of February 10, 2020, 63,727 of which are unvested, but early exercisable.

(4) Consists of (i) 99,965 shares of our common stock held of record by John W. Smither and (ii) 189,931 shares of our common stock subject to options that are exercisable within 60 days of February 10, 2020, 188,682 of which are unvested, but early exercisable.

(5) Consists of 159,943 shares of our common stock subject to options that are exercisable within 60 days of February 10, 2020, of which all are unvested, but early exercisable.

(6) Consists of (i) 144,882 shares of our common stock held of record by Howard G. Welgus, (ii) 24,991 shares of our common stock held of record by the Welgus Living Trust, UA 02-15-2011, and (iii) 182,718 shares of our common stock subject to options that are exercisable within 60 days of February 10, 2020, of which 160,366 shares are unvested, but early exercisable.

(7) Consists of (i) 901,391 shares of our common stock held of record by Bhaskar Chaudhuri, (ii) 49,981 shares of our common stock held of record by the Chaudhuri Family Trust Dated January 12, 2001, and (ii) 99,965 shares of our common stock subject to options that are exercisable within 60 days of February 10, 2020, all of which are unvested.

(8) Does not include shares of common stock held by FLS LP (as defined below). Daniel J. Estes is a Partner at Frazier Healthcare Partners. See footnote 15. Dr. Estes disclaims beneficial ownership of the shares held by FLS LP.

(9) Consists of 10,542,790 shares of our common stock held by Frazier Life Sciences VIII, LP, or FLS LP. The general partner of FLS LP is FHM Life Sciences VIII, LP, or FHM LP. The general partner of FHM LP is FHM Life Sciences VIII, LLC. James Topper and Patrick J. Heron are the sole managing members of FHM Life Sciences VIII, LLC and share voting and investment power with respect to such shares held by FLS LP. Dr. Topper and Mr. Heron disclaim beneficial ownership of such shares except to the extent of their pecuniary interest in such shares. The principal business address of FLS LP is Two Union Square, 601 Union Street, Suite 3200, Seattle, WA 98101.

(10) Jonathan T. Silverstein is a member of OrbiMed Advisors LLC and a member of our board of directors. See footnote 16.

(11) Does not include shares of common stock held by the Bain Capital Life Sciences Entities (as defined below). Ricky Sun is a Partner with Bain Capital Life Sciences Investors, LLC.

(12) Does not include shares held by HBM Healthcare Investments (Cayman) Ltd. Alexander G. Asam is an investment advisor to HBM Partners AG. HBM Partners AG acts as an investment advisor to HBM Healthcare Investments (Cayman) Ltd. Dr. Asam has no voting or investment power over the shares held by HBM Healthcare Investments (Cayman) Ltd. and disclaims beneficial ownership of such shares.

(13) Includes 1,318,413 shares subject to options held by all executive officers and directors that are exercisable within 60 days of February 10, 2020, of which 1,291,481 shares are unvested, but early exercisable.

(14) Consists of (i) 3,609,796 shares of our common stock held by Bain Capital Life Sciences Fund, L.P., or BC LS, and (ii) 369,496 shares of our common stock held by BCIP Life Sciences Associates, LP, or BCIP LS, and together with BC LS, the Bain Capital Life Sciences Entities. Bain Capital Life Sciences Investors, LLC, whose managers are Jeffrey Schwartz and Adam Koppel, is the ultimate general partner of BC LS and governs the investment strategy and decision-making process with respect to investments held by BCIP LS. AS a result, each of Bain Capital Life Sciences Investors, LLC, Mr. Schwartz and Dr. Koppel may be deemed to share voting and dispositive power over the shares held by the Bain Capital Life Sciences Entities. The address of the Bain Capital Life Sciences Entities is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.

(15) Consists of 10,542,790 shares of our common stock held by Frazier Life Sciences VIII, LP, or FLS LP. The general partner of FLS LP is FHM Life Sciences VIII, LP, or FHM LP. The general partner of FHM LP is FHM Life Sciences VIII, LLC. James Topper and Patrick J. Heron are the sole managing members of FHM Life Sciences VIII, LLC and share voting and investment power with respect to such shares held by FLS LP. Dr. Topper and Mr. Heron disclaim beneficial ownership of such shares except to the extent of their pecuniary interest in such shares. The principal business address of FLS LP is Two Union Square, 601 Union Street, Suite 3200, Seattle, WA 98101.

(16) Consists of (i) 4,067,564 shares of our common stock held by OrbiMed Private Investments VII, LP, or OPI VII, and (ii) 606,286 shares of our common stock held by OrbiMed Partners Master Fund Limited, or OPMF. OrbiMed Capital GP VII LLC, or OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors LLC, or OrbiMed Advisors, a registered investment advisor under the Investment Advisors Act of 1940, as amended, is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by OPI VII and as a result may be deemed to have beneficial ownership over such securities. OrbiMed Capital LLC, or OrbiMed Capital, is the sole holder of manager shares and sole voting member of OPMF. OrbiMed Capital is a relying adviser of OrbiMed Advisors. OrbiMed Advisors and OrbiMed Capital exercise voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI VII and OPMF. The business address of these entities is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

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

In addition to the compensation arrangements, including employment agreements, with our directors and executive officers, including those discussed in the section entitled "Executive Compensation," the following is a description of each transaction since January 1, 2017 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of our total assets; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which are described where required under the section entitled "Executive Compensation."

Participation in IPO

Certain of our stockholders, including entities affiliated with holders of 5% or more of our capital stock and certain of our directors, purchased an aggregate of $30.7 million shares of our common stock in our IPO at the IPO price and on the same terms as the other purchasers in our IPO and not pursuant to any pre-existing contractual rights or obligations.

In addition, certain friends and family of our directors or officers, and certain of our other non-executive officer employees purchased an aggregate of 111,764 shares of our common stock in our IPO at the IPO in a directed share program.

Series C Convertible Preferred Stock Financing

In October 2019, we sold an aggregate of 8,122,963 shares of our Series C convertible preferred stock at a purchase price of $11.6337 per share for an aggregate gross purchase price of approximately $94.5 million. Each share of our Series C convertible preferred stock converted automatically into one share of our common stock upon the completion of our initial public offering.

The purchasers of our Series C convertible preferred stock are entitled to specified registration rights. For additional information, see "Description of Capital Stock—Registration Rights." The following table summarizes the Series C convertible preferred stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series C convertible preferred stock. Please refer to the section titled "Principal Stockholders" for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series C Convertible Preferred Stock	Total Purchase Price ($)
Bain Capital Life Sciences Fund, L.P.(1)	779,758	9,071,449
BCIP Life Sciences Associates, LP(1)	79,815	928,548
Frazier Life Sciences VIII, L.P.(2)	1,074,467	12,500,000
OrbiMed Private Investments VII, LP(3)	859,573	9,999,996
OrbiMed Partners Master Fun, Ltd(3)	429,786	4,999,995
HBM Healthcare Investments (Cayman), Ltd.(4)	1,289,360	14,999,998

(1) Ricky Sun, a member of our board of directors, is a Partner at Bain Capital Life Sciences Investors, LLC. The Bain entities hold an aggregate of more than 5% of our outstanding capital stock.
(2) Daniel J. Estes and Patrick J. Heron, both members of our board of directors, is a General Partner and the Managing General Partner, respectively, at Frazier Health Life Sciences. Frazier Life Sciences VIII, L.P. holds more than 5% of our outstanding capital stock.
(3) Jonathan T. Silverstein, a member of our board of directors, is a Managing Partner and Co-Head of Global Private Equity at OrbiMed Advisors LLC. OrbiMed Private Investments VII, LP, or OPI VII, holds more than 5% of our outstanding capital stock. OrbiMed Capital

GP VII LLC, or OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors LLC, or OrbiMed Advisors, a registered investment advisor under the Investment Advisors Act of 1940, as amended, is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by OPI VII and as a result may be deemed to have beneficial ownership over such securities. OrbiMed Partners Master Fund Limited, or OPMF, holds 859,874 of our outstanding capital stock. OrbiMed Capital LLC, or OrbiMed Capital, is the sole holder of manager shares and sole voting member of OPMF. OrbiMed Capital is a relying adviser of OrbiMed Advisors. OrbiMed Advisors and OrbiMed Capital exercise voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI VII and OPMF.

(4) Alexander G. Asam, a member of our board of directors, is an investment advisor to HBM Partners AG. HBM Partners AG acts as an investment advisor to HBM Healthcare Investments (Cayman) Ltd. Dr. Asam has no voting or investment power over the shares held by HBM Healthcare Investments (Cayman) Ltd. and disclaims beneficial ownership of such shares.

Series B Convertible Preferred Stock Financing

In September 2018, we sold an aggregate of 9,364,850 shares of our Series B convertible preferred stock at a purchase price of $6.19 per share for an aggregate purchase price of approximately $58.0 million. Each share of our Series B convertible preferred stock converted automatically into one share of our common stock upon the completion of our initial public offering.

The purchasers of our Series B convertible preferred stock are entitled to specified registration rights. For additional information, see “Description of Capital Stock—Registration Rights.” The following table summarizes the Series B convertible preferred stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series B convertible preferred stock. Please refer to the section titled “Principal Stockholders” for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series B Convertible Preferred Stock	Total Purchase Price ($)
Bain Capital Life Sciences Fund, L.P.(1)	2,563,231	15,875,035
BCIP Life Sciences Associates, LP(1)	262,371	1,624,961
Frazier Life Sciences VIII, L.P.(2)	2,099,019	12,999,997
OrbiMed Private Investments VII, LP(3)	2,825,603	17,499,999

(1) Ricky Sun, a member of our board of directors, is a Partner at Bain Capital Life Sciences Investors, LLC. The Bain entities hold an aggregate of more than 5% of our outstanding capital stock.

(2) Daniel J. Estes and Patrick J. Heron, both members of our board of directors, is a Partner and the Managing General Partner, respectively, at Frazier Health Life Sciences. Frazier Life Sciences VIII, L.P. holds more than 5% of our outstanding capital stock.

(3) Jonathan T. Silverstein, a member of our board of directors, is a Managing Partner and Co-Head of Global Private Equity at OrbiMed Advisors LLC. OrbiMed Private Investments VII, LP, or OPI VII, holds more than 5% of our outstanding capital stock. OrbiMed Capital GP VII LLC, or OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors LLC, or OrbiMed Advisors, a registered investment adviser under the Investment Advisors Act of 1940, as amended, is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by OPI VII and as a result may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein. Each of OrbiMed GP VII, OrbiMed Advisors, Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein disclaims beneficial ownership of the shares held by OPI VII, except to the extent of its or his pecuniary interest therein if any.

Series A Convertible Preferred Stock Financing

In two closings in April 2017 and March 2018, we sold an aggregate of 6,747,629 shares of our Series A convertible preferred stock at a purchase price of $2.00 per share for an aggregate purchase price of approximately $13.5 million. In addition, we issued an aggregate of 149,946 shares of our Series A convertible preferred stock to certain holders of convertible promissory notes. Each share of our Series A convertible preferred stock converted automatically into one share of our common stock upon the completion of our initial public offering.

The purchasers of our Series A convertible preferred stock are entitled to specified registration rights. For additional information, see “Description of Capital Stock—Registration Rights.” The following table summarizes the Series A convertible preferred stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series A convertible preferred stock. Please refer to the section titled “Principal Stockholders” for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series A Convertible Preferred Stock	Total Purchase Price ($)
Bhaskar Chaudhuri(1)	37,486	37,500
Chaudhuri Family Trust(2)	49,981	100,000
David W. Osborne(3)	24,991	50,000
Frazier Life Sciences VIII, L.P.(4)	6,360,272	12,612,500
Todd Franklin Watanabe(5)	99,964	200,000
Watanabe Ventures, LLC(5)	49,981	100,000
Welgus Living Trust(6)	24,991	50,000

(1) Bhaskar Chaudhuri is a member of our board of directors. Consists of 37,486 shares of Series A Preferred Stock from cancellation of indebtedness of a convertible promissory note held by Dr. Chaudhuri. Such shares are calculated by multiplying the dollar amount of the indebtedness cancelled by the discounted price of $0.50 per share applicable to cancellation of indebtedness.
(2) Bhaskar Chaudhuri is a member of our board of directors and is the trustee of the Chaudhuri Family Trust.
(3) David W. Osborne is our Chief Technical Officer.
(4) Daniel J. Estes, a member of our board of directors and Patrick J. Heron, the chairman of our board of directors, is a General Partner and the Managing General Partner, respectively, at Frazier Health Life Sciences. Frazier Life Sciences VIII, L.P. holds more than 5% of our outstanding capital stock. Includes 112,460 shares of Series A Preferred Stock from cancellation of indebtedness of a convertible promissory note held by Frazier Life Sciences VIII, L.P. Such shares are calculated by multiplying the dollar amount of the indebtedness cancelled by the discounted price of $1.00 per share applicable to cancellation of indebtedness.
(5) Todd Franklin Watanabe is our President and Chief Executive Officer and a member of our board of directors. Mr. Watanabe is the Chief Operating Officer of Watanabe Ventures, LLC.
(6) Howard G. Welgus is our Chief Medical Officer and a trustee of the Welgus Living Trust.

Convertible Note Financing

In August 2016, we issued convertible promissory notes to Bhaskar Chaudhuri and Frazier Life Sciences VIII, L.P. in an aggregate principal amount of $150,000. In April 2017, the convertible promissory notes were extinguished and the entire principal amounts thereof were converted into an aggregate of 149,946 shares of our Series A convertible preferred stock.

Transactions with Hawkeye Therapeutics, Inc.

In June 2019, we entered into a collaboration agreement, or the Hawkeye Agreement, with Hawkeye Therapeutics, Inc., or Hawkeye, to collaborate on the research and development of one or more new applications of roflumilast. In consideration for their services to be performed under the Hawkeye Agreement, each of Arcutis Biotherapeutics, David W. Osborne, our Chief Technical Officer, and Bhaskar Chaudhuri, a member of our board of directors, purchased 995,000, 250,000 and 500,000 shares of common stock in Hawkeye, respectively, pursuant to a stock purchase agreement. Additionally, one of our stockholders, Frazier Life Sciences VIII, L.P., is a stockholder in Hawkeye, and Bhaskar Chaudhuri, Daniel J. Estes and Patrick J. Heron, each a member of our board of directors, are affiliated with Frazier Life Sciences VIII, L.P. For more information, please see Note 6 to the financial statements.

Investors' Rights Agreement

We have entered into an amended and restated investors' rights agreement, dated October 8, 2019, with certain holders of our convertible preferred stock, including entities with which certain of our executive officers and directors are affiliated. These stockholders are entitled to rights with respect to the registration of their shares following the initial public offering under the Securities Act. For a description of these registration rights, see the section entitled "Description of Capital Stock—Registration Rights."

Equity Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain directors, as more fully described in the sections entitled "Executive Compensation" and "Management—Non-Employee Director Compensation," respectively.

Director and Executive Officer Compensation

Please see the sections entitled "Management—Non-Employee Director Compensation" and "Executive Compensation" for information regarding the compensation of our directors and executive officers.

Employment Agreements

We have entered into amended and restated employment offer letters with our executive officers. For more information regarding these agreements, see the section entitled "Executive Compensation—Employee Offer Letters."

Indemnification Agreements

In connection with our initial public offering, we entered into new indemnification agreements with each of our directors and executive officers. The indemnification agreements, our restated certificate of incorporation and our restated bylaws will require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and officers. For more information regarding these agreements, see the section entitled "Executive Compensation—Limitations on Liability and Indemnification Matters" for information on our indemnification arrangements with our directors and executive officers.

Policies and Procedures for Related Party Transactions

In connection with our initial public offering, we adopted a written related person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. We expect the policy to provide that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate family members or affiliates in which the amount involved exceeds $120,000 will be presented to our audit committee (or the committee composed solely of independent directors, if applicable) for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee (or the committee composed solely of independent directors, if applicable) will consider the relevant facts and circumstances available and deemed relevant to the audit committee (or the committee composed solely of independent directors, if applicable), including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth all fees billed for professional audit services and other services rendered by Ernst & Young LLP:

	Year Ended December 31,	
	2019	2018
Audit Fees [1]	$ 1,177,000	$ 500,000
Tax Fees [2]	28,040	—
Total Fees	$ 1,205,040	$ 500,000

[1] Audit fees are for professional services for the audit of the Company's financial statements, the review of quarterly interim financial statements, and for services that are normally provided by the accountant in connection with other regulatory filings or engagements. Fees for the year ended December 31, 2019 include services associated with our IPO. Fees for the year ended December 31, 2018 include services rendered for the initial 2017 and 2018 audits.

[2] Tax fees are for compliance and consultation.

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.				X
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	
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

† 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, 2019 and 2018, the related statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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
March 19, 2020

ARCUTIS BIOTHERAPEUTICS, INC.

Balance Sheets
(In thousands, except share and per share data)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,336	$ 39,394
Marketable securities	37,929	11,546
Prepaid expenses and other current assets	5,209	158
Total current assets	106,474	51,098
Property, plant, and equipment, net	227	—
Operating lease right-of-use asset	264	—
Other assets	47	—
Total assets	$ 107,012	$ 51,098
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,405	$ 1,801
Accrued liabilities	3,654	872
Operating lease liability	178	—
Total current liabilities	5,237	2,673
Operating lease liability, noncurrent	129	—
Other long-term liabilities	184	160
Total liabilities	5,550	2,833
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.0001 par value; 48,787,898 and 32,536,270 shares authorized at December 31, 2019 and 2018, respectively; 24,385,388 and 16,262,425 shares issued and outstanding at December 31, 2019 and 2018, respectively; aggregate liquidation preference of $166,300 and $71,800 at December 31, 2019 and 2018, respectively	166,491	72,252
Stockholders' deficit:		
Common stock, $0.0001 par value; 65,820,000 and 44,000,000 shares authorized at December 31, 2019 and 2018, respectively; 2,879,763 and 2,615,651 shares issued at December 31, 2019 and 2018, respectively; 2,120,853 and 1,557,900 shares outstanding at December 31, 2019 and 2018, respectively	—	—
Additional paid-in capital	1,244	289
Accumulated other comprehensive loss	(1)	—
Accumulated deficit	(66,272)	(24,276)
Total stockholders' deficit	(65,029)	(23,987)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 107,012	$ 51,098

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,		
	2019	2018	2017
Operating expenses:			
Research and development	$ 36,522	$ 17,940	$ 3,411
General and administrative	6,610	1,795	695
Total operating expenses	43,132	19,735	4,106
Loss from operations	(43,132)	(19,735)	(4,106)
Other income (expense), net	1,136	480	(872)
Net loss	$ (41,996)	$ (19,255)	$ (4,978)
Other comprehensive loss:			
Unrealized loss on marketable securities, net of tax	(1)	—	—
Comprehensive loss	$ (41,997)	$ (19,255)	$ (4,978)
Net loss per share, basic and diluted	$ (22.78)	$ (15.53)	$ (7.16)
Weighted-average shares used in computing net loss per share, basic and diluted	1,843,213	1,239,689	695,305

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

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance—December 31, 2016	—	$ —	509,033	$ —	$ 1	$ —	$ (43)	$ (42)
Issuance of Series A convertible preferred stock, net of issuance costs of $115 and convertible preferred stock liability of $219	3,590,845	6,850	—	—	—	—	—	—
Issuance of Series A convertible preferred stock upon conversion of convertible promissory notes	149,946	304	—	—	—	—	—	—
Vesting of founder shares subject to repurchase	—	—	413,589	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	27	—	—	27
Net loss	—	—	—	—	—	—	(4,978)	(4,978)
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 short term investments	—	—	—	—	—	(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)

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

ARCUTIS BIOTHERAPEUTICS, INC.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (41,996)	$ (19,255)	$ (4,978)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	68	—	—
Right-of-use asset amortization	127	—	—
Net amortization/accretion on marketable securities	(354)	(14)	—
Stock-based compensation	824	151	27
Issuance of convertible preferred stock in connection with license agreement	—	3,000	—
Change in fair value of convertible preferred stock liability	—	(75)	747
Change in fair value of derivative liability	—	—	150
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,304)	243	(401)
Other assets	(47)	—	—
Accounts payable	(458)	1,264	537
Accrued liabilities	2,388	601	143
Operating lease liabilities	(84)	—	—
Net cash used in operating activities	(42,836)	(14,085)	(3,775)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of marketable securities	(60,830)	(11,532)	—
Proceeds from maturities of marketable securities	34,800	—	—
Purchases of property and equipment	(295)	—	—
Net cash used in investing activities	(26,325)	(11,532)	—
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock upon exercise of stock options	265	386	—
Proceeds from issuance of Series A convertible preferred stock, net of issuance costs	—	6,295	7,069
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	54,912	—
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	94,239	—	—
Proceeds from issuance of convertible promissory note payable	—	—	50
Deferred financing costs	(1,401)	—	—
Net cash provided by financing activities	93,103	61,593	7,119
Net increase in cash and cash equivalents	23,942	35,976	3,344
Cash and cash equivalents at beginning of period	39,394	3,418	74
Cash and cash equivalents at end of period	$ 63,336	$ 39,394	$ 3,418
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:			
Conversion of convertible promissory notes payable into convertible preferred stock	$ —	$ —	$ 304
Convertible preferred stock liability recorded in connection with convertible preferred stock	$ —	$ —	$ 219
Reclassification of convertible preferred stock liability to Series A convertible preferred stock	$ —	$ 891	$ —
Right-of-use asset obtained in exchange for lease liability	$ 391	$ —	$ —
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 Consolidated 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. In October 2019, the Company changed its name from Arcutis, Inc. to Arcutis Biotherapeutics, Inc. The Company's current portfolio is comprised of topical treatments with significant promise in addressing immune-mediated dermatological diseases and conditions, or immuno-dermatology. The Company's strategy is to advance treatments that leverage validated biological targets in dermatology while delivering a clinical profile that addresses 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, all while maximizing its probability of technical success.

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

Initial Public Offering

On January 31, 2020, the Company completed an initial public offering, or IPO, through 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' partial exercise of their option to purchase additional shares. The aggregate gross proceeds received by the Company from the offering were approximately $183.3 million, before deducting underwriting discounts, commissions and offering related transaction costs. Upon the closing of the IPO, all of the outstanding shares of convertible preferred stock automatically converted into shares of common stock. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding. The financial statements as of December 31, 2019, including share and per share amounts, do not include the effects of the IPO. See Note 13, "Subsequent Events".

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $66.3 million and $24.3 million as of December 31, 2019 and 2018, respectively. The Company had cash, cash equivalents and marketable securities of $101.3 million and $50.9 million as of December 31, 2019 and 2018, respectively. Prior to our IPO completed in January 2020, 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, including the cash proceeds received from the IPO in February 2020, 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.

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, or U.S. GAAP.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the 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 initial public offering completed in January 2020), fair value of convertible preferred stock liability, 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 government debt securities.

Marketable Securities

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

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on marketable securities are included in other income (expense), net. To date, no such other than temporary declines in fair value have occurred or have been recorded. The cost of investments sold is based on the specific-identification method. As of December 31, 2019, there was $1,000 of unrealized losses on marketable securities, which is reported as a component of other comprehensive loss on the balance sheet. There were no unrealized gains or losses on marketable securities for the years ended December 31, 2018 and 2017. There were no realized gains or losses on investments for the years ended December 31, 2019, 2018 and 2017. Interest on marketable securities is included in Other income (expense), net.

Concentration of Credit Risk and Other Risks and Uncertainties

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

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

Fair Value Measurement

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

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

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

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

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

Leases

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

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

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

Preclinical and Clinical Accruals and Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical 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, 2019, 2018 and 2017, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Convertible Preferred Stock

The Company classifies convertible preferred stock outside of stockholders' deficit on its balance sheets as the requirements of triggering a deemed liquidation event, as defined within its amended and restated certificate of incorporation, are not entirely within the Company's control. In the event of such a deemed liquidation event, the proceeds from the event are distributed in accordance with the liquidation preferences (see Note 8), provided that the holders of convertible preferred stock have not converted their shares into common stock. The Company records the issuance of convertible preferred stock at the issuance price less related issuance costs. The Company has not adjusted 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 occur.

Convertible Preferred Stock Liability

The freestanding rights of Series A convertible preferred stockholders to purchase additional shares of the Company's Series A convertible preferred stock in a subsequent closing, contingent upon approval by the board of directors, at a fixed price per share, are accounted for as a liability at fair value as the shares underlying the right contain contingent redemption features outside the control of the Company. The liability was subject to re-measurement at each balance sheet date until settlement, with changes in fair value recognized as a component of other income (expense), net in the statements of operations. In March 2018, the convertible preferred stock liability was settled upon the issuance of the second tranche of Series A convertible preferred stock and the fair value of the liability was reclassified to the Series A convertible preferred 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. Additionally, if expectations change such that the Company does not expect goods to be delivered or services to be rendered, such prepayments are charged to expense.

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.

Variable Interest Entities

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

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.

Comprehensive Loss

Comprehensive loss consists of net loss and other comprehensive income or loss and, as of December 31, 2019, was comprised of $1,000 of unrealized losses on marketable securities.

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 Issued Accounting Pronouncements

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 will require 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 will now include forward-looking information in the determination of their credit loss estimates. Many of the loss estimation techniques applied today will still be permitted, although the inputs to those techniques will change 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. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. This update clarified the effective date of ASU No. 2016-13 for nonpublic business entities to fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021. Early application of ASU No. 2016-13 will be permitted for all organizations for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company does not expect a material impact on its financial statements from adopting this standard.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* or ASU No. 2018-13, which removes, modifies, and adds various disclosure requirements on fair value measurements in Topic 820. ASU No. 2018-13 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this update. An entity is permitted to early adopt any removed or modified disclosures upon issuance of this update and delay adoption of the additional disclosures until their effective date. The Company does not expect a material impact on its financial statements from adopting this update.

In December 2019, the FASB issued *ASU No. 2019-12, Income Taxes (Topic 740)* which amends the existing guidance relating to the accounting for income taxes. This standard is intended to simplify the accounting for income taxes by removing certain exceptions to the general principles of accounting for income taxes and to improve the consistent application of GAAP for other areas of accounting for income taxes by clarifying and amending existing guidance. The standard is effective for public business entities, for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. 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 does not expect a material impact on its financial statements from adopting this standard.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02, *Leases* (Topic 842) (ASC 842), which establishes a comprehensive new lease accounting model. The new standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The new standard is effective

for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, an update which provides another transition method, the prospective transition method, which allows entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company early adopted this guidance as of January 1, 2019. Refer to Note 7 for more information.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments—Overall* (Topic 825)*—Recognition and Measurement of Financial Assets and Financial Liabilities*, which amends the guidance in U.S. GAAP on the classification and measurement of financial instruments. The new standard revises an entity's accounting related to (i) the classification and measurement of investments in equity securities and (ii) the presentation of certain fair value changes for financial liabilities measured at fair value. The new standard also amends certain disclosure requirements associated with the fair value of financial instruments. The new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted for all entities whose financial statements have not yet been issued or have not been made available for issuance with respect to certain changes made to ASC 825. The Company early adopted this guidance as of January 1, 2018. Refer to Note 3 for more information and disclosures related to this amended guidance.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation* (Topic 718)*—Improvements to Employee Share Based Payment Accounting* as part of the FASB simplification initiative. The new standard provides for changes to accounting for stock compensation including (i) excess tax benefits and tax deficiencies related to share based payment awards will be recognized as income tax expense or benefit in the reporting period in which they occur; (ii) excess tax benefits will be classified as an operating activity in the statement of cash flows; (iii) the option to elect to estimate forfeitures or account for them when they occur; and (iv) increase of the tax withholding requirements threshold to qualify for equity classification. The standard is effective for fiscal years beginning after December 15, 2017 and interim periods within fiscal years beginning after December 15, 2018. The Company early adopted this guidance as of January 1, 2017 and the impact of its adoption on the Company's financial statements was not material. The Company elected a policy to account for forfeitures as they occur.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*. This standard is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of Topic 718, (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The standard is effective for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606. The Company early adopted this standard on January 1, 2018 and the impact of its adoption on the Company's financial statements was not material.

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

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Consolidated Financial Statements

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$ 20,509	$ —	$ —	$ 20,509
Commercial paper	—	15,431	—	15,431
Government securities	15,000	—	—	15,000
Total assets	$ 35,509	$ 15,431	$ —	$ 50,940

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

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

The following table summarizes the estimated value of the Company's cash, cash equivalents and marketable securities and the gross unrealized holding gains and losses (in thousands):

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

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

	December 31, 2018			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Commercial paper	$ 3,885	—	—	$ 3,885
Money market funds(1)	20,509	—	—	20,509
Government securities	15,000	—	—	15,000
Total cash and cash equivalents	39,394	—	—	39,394
Marketable securities:				
Commercial paper	11,546	—	—	11,546
Total marketable securities	$ 11,546	$ —	$ —	$ 11,546

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

The following table summarizes the change in the fair value of the convertible preferred stock liability for the years ended December 31, 2018 and 2017 (in thousands). There was no activity for the year ended December 31, 2019.

	Year Ended December 31,	
	2018	2017
Beginning balance	$ 966	$ —
Fair value at issuance	—	219
Loss (gain) from changes in fair value	(75)	747
Recognition of fair value upon issuance of convertible preferred stock	(891)	—
Ending balance	$ —	$ 966

The fair value of the Company's convertible preferred stock liability is based on significant inputs not observed in the market, and thus represents a Level 3 measurement. The Company estimates the fair value of this liability using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31,	
	2018	2017
Expected term (in years)	4.1	1.0 - 4.0
Expected volatility	65.4 %	63.2 - 69.8%
Risk-free interest rate	2.53 %	1.42 - 2.15%
Dividend yield	— %	— %

The following table summarizes the change in the fair value of the derivative liability for the year ended December 31, 2017 (in thousands). There was no activity for the year ended December 31, 2019 or the year ended December 31, 2018.

	Year Ended December 31, 2017
Beginning balance	$ —
Loss from changes in fair value	150
Reclassification to convertible preferred stock upon conversion of the convertible promissory notes	(150)
Ending balance	$ —

The fair value of the Company's derivative liability is based on significant inputs not observed in the market, and thus represents a Level 3 measurement. Refer to Note 5 for further discussion on the derivative liability and related valuation.

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2019	2018
Prepaid clinical trial costs	$ 2,998	$ 40
Deferred financing costs	1,747	—
Other prepaid expenses and current assets	464	118
Total prepaid expenses and other current assets	5,209	158

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2019	2018
Accrued compensation	$ 1,379	$ 455
Clinical trial accruals	1,497	250
Early exercise liability, current	225	116
Accrued expenses and other current liabilities	553	51
Total accrued liabilities	$ 3,654	$ 872

5. Convertible Promissory Notes Payable to Related Parties

In August 2016, the Company entered into a Convertible Promissory Note Purchase Agreement, or the Purchase Agreement, with a founder and an investor, or the Holders, who are related parties. Under the terms of the Purchase Agreement, the Company could issue up to $1.0 million of convertible promissory notes, or the Notes, with a one-year maturity. The Notes bear interest at a rate of 6.0% per annum, compounded annually, and payable at maturity. In the event of an equity financing with minimum proceeds in an amount approved by the Company's board of directors, the outstanding balance of the Notes is automatically converted into shares of stock issued in the equity financing based on a conversion price equal to 50% of the issuance price paid by investors in said financing.

The Company issued Notes in the amount of $100,000 in August 2016 and $50,000 in March 2017. The redemption of the Notes upon an equity financing was determined to be a contingent redemption feature that was not clearly and closely related to the Notes and was bifurcated and recognized as a derivative liability on the balance sheet. The fair value of the derivative liability was estimated to be insignificant on the issuance dates of August 2016 and March 2017.

In April 2017, the Company issued 3,590,845 shares of Series A convertible preferred stock to investors at $2.00 per share for net proceeds of $7.1 million. At the time of conversion, the value of the derivative liability was determined to be $150,000 and the increase in fair value was recorded as other operating expense. Accordingly, the outstanding principal balance of $150,000 of the Notes was automatically converted into 149,946 shares of Series A convertible preferred stock and the derivative liability was settled. The carrying value of the Notes of $154,000 and the derivative liability of $150,000 were reclassified to Series A convertible preferred stock.

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

The Company paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of Series B preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. The company subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2B study of ARQ-151 in plaque psoriasis in August 2019 for the achievement of positive

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

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., or Hengrui, whereby Hengrui granted the Company an exclusive option to obtain certain exclusive rights to research, develop and commercialize products containing the compound designated by Hengrui as SHR0302, a JAK inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, and the European Union (including for clarity the United Kingdom). The initial option period under the agreement extended to June 2019, and was subsequently amended to extend until January 2020. The Company made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui License Agreement which was recorded as research and development expense. In December 2019, the Company exercised its exclusive option under the agreement, for which it made a $1.5 million cash payment, which was recorded in research and development expense, and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, the Company has agreed to make cash payments of up to an aggregate of $20.5 million upon achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $200 million in sales-based milestones based on certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products the Company commercializes under the Hengrui License Agreement, it will pay tiered royalties to Hengrui on net sales of each licensed product by the Company, or its affiliates, or its sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the later of (1) expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, the Company is obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income it receives from sublicensees of its rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

Hawkeye Collaboration Agreement

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

Contemporaneously with the execution of the Hawkeye Agreement, the Company entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye's common stock at $0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye. In the event that Hawkeye issues shares of Series A preferred stock with proceeds over $5.0 million, Hawkeye is required to issue to the Company a number of fully-paid fully-vested shares of common stock determined by dividing (i) $2,000,000 by (ii) an amount equal to the cash price

per share for Series A preferred stock, the value of which was determined to be immaterial as of December 31, 2019. Other than the potential issuance of this common stock, there are no upfront payments, milestones or royalties pursuant to the Hawkeye Agreement. The Company determined that Hawkeye is a variable interest entity for which consolidation is not required as it is not the primary beneficiary.

7. Commitments and Contingencies

Operating Lease

The Company leases one facility in Westlake Village, California under an operating lease that commenced in February 2019 and has a non-cancelable lease term of 30 months, subject to fixed escalation increases. The lease contains an option to extend for an additional term, however, the Company is not reasonably certain to exercise the option for the lease.

The minimum annual rental payments of the Company's operating lease liability as of December 31, 2019 are as follows (in thousands):

	Amounts
2020	$ 192
2021	132
Total minimum lease payments	324
Less: Amounts representing interest	(17)
Present value of future minimum lease payments	$ 307
Current portion operating lease liability	178
Operating lease liability, noncurrent	129
Total operating lease liability	$ 307

Straight-line rent expense recognized for operating leases was $151,000 for the year ended December 31, 2019. There were no variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the year ended December 31, 2019.

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

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

The following summarizes additional information related to the operating lease:

	December 31, 2019
Weighted-average remaining lease term (in years)	1.67
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 the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

8. Convertible Preferred Stock and Stockholders' Deficit

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

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

Convertible preferred stock as of December 31, 2018 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
Total	32,536,270	16,262,425	$ 72,252	$ 71,800

In connection with the IPO in January 2020, all of the Company's outstanding shares of convertible preferred stock were automatically converted into 24,385,388 shares of common stock. See Note 13.

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

The Series A investors were also granted freestanding rights to participate in additional tranches to raise a minimum of $3.3 million, upon election by the board of directors including at least one of the Series A directors, by purchasing 1,657,314 shares of Series A convertible preferred stock at $2.00 per share in two tranches, provided such election occurs prior to April 2019. The two tranches consisted of 828,654 shares and 828,660 shares, respectively. The Company concluded that the investors' rights to purchase Series A convertible preferred shares met the definition of a freestanding financial instrument, as they were legally detachable and separately exercisable from the Series A convertible preferred stock, or the Series A Convertible Preferred Stock Liability. As the Series A Convertible Preferred Stock Liability was redeemable at the election of holders of the then-outstanding shares, it represented a liability to be accounted for at fair value and remeasured at each reporting period.

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

In March 2018, the Company completed the second tranche closing and issued 3,156,784 shares of Series A convertible preferred stock to the investors at a purchase price of $2.00 per share for net proceeds of $6.3 million.

The Series A Convertible Preferred Stock Liability was remeasured to fair value just prior to settlement and the carrying value of the liability of $891,000 was reclassified to Series A convertible preferred stock. Concurrently with the closing of the second tranche, the Company amended the Series A convertible preferred stock purchase agreement to merge the second and third tranches and increased the maximum number of shares to be issued in the second tranche to 3,156,784 shares. For the years ended December 31, 2018 and 2017, the Company recorded a gain of $75,000 and a net loss of $747,000, respectively, in the statement of operations for the change in fair value of the liability.

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

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

Significant provisions of the Company's convertible preferred stock are as follows:

Conversion Rights

Each share of convertible preferred stock is convertible into shares of common stock determined by dividing the original issuance price by the conversion price. The conversion price is equal to the original issuance price, which is $2.00 for Series A convertible preferred stock, $6.19 for Series B convertible preferred stock and $11.63 for Series C convertible preferred stock. All series of convertible preferred stock will convert into shares of common stock on a one-to-one basis. The conversion price will be adjusted for stock splits, distributions, dividends, noncash distributions, share purchase rights, and capital reorganizations. In addition, the conversion price for each series of convertible preferred stock will be reduced upon the issuance or sale by the Company of common shares or instruments convertible or exercisable into common shares, for consideration or with an exercise price that is less than the conversion price applicable to such series. Such reduction may result in recognition by the Company of a deemed dividend to convertible preferred stockholders, if the resulting conversion price is less than the fair value per share of common stock as of the date convertible preferred stock was issued.

Conversion can occur at any time at the option of each holder. In addition, all shares of convertible preferred stock will convert automatically upon (a) the closing of a Qualified Public Offering or (b) by vote or written consent of the holders of a majority of the then outstanding shares of Series A, B and C convertible preferred stock. Such conversion of all outstanding convertible preferred stock occurred in January 2020 upon the closing of our initial public offering.

Liquidation Rights

In the event of any liquidation (including a change in control), dissolution, or winding up of the Company, either voluntary or involuntary, each stockholder of Series A , B and C convertible preferred stock will be entitled to receive, prior and in preference to any distribution of any assets or surplus funds to the holders of common stock, an amount per share equal to the applicable original issue price of $2.00, $6.19 and $11.63 per share for the Series A, B and C convertible preferred stock, respectively, in addition to all declared but unpaid dividends. If the full amount is not available for distribution the entire assets and funds legally available will be distributed ratably among the holders of Series C convertible preferred stock first, followed by the holders of Series B convertible preferred stock, then if any amount is left preferential payments will be made to Series A convertible preferred stockholders. After the distributions described above have been paid in full, the remaining assets of the Company will be distributed among the common stockholders and convertible preferred stockholders pro rata based on the number of shares held by each holder on an as-converted to common stock on a one-to-one basis.

Voting Rights

Each share of Series A, B and C convertible preferred stock has the right to one vote for each share of common stock into which such convertible preferred stock could be converted and with respect to such

vote, such holder will have full voting rights and powers equal to holders of common stock. With regard to the election of directors: (i) the holders of a majority of the Series C convertible preferred stock, voting as a separate class, are entitled to elect one member to the Company's Board of Directors (ii) the holders of a majority of the Series B convertible preferred stock, voting as a separate class, are entitled to elect two directors; (iii) the holders of a majority of the Series A convertible preferred stock, voting as a separate class, are entitled to elect two directors; (iv) the holders of a majority of the common stock, voting as a separate class, are entitled to elect two directors; and (v) the holders of a majority of the shares of common stock and convertible preferred stock, exclusively and voting together as a single class, are entitled to elect the remaining directors. There is a total of eight members on the Company's Board of Directors.

Dividend Rights

Each stockholder of Series A, B and C convertible preferred stock is entitled to receive dividends when, as and if declared by the board of directors at the rate that is higher of (i) 6% of the original issue price per annum or (ii) pro rata dividend rate on an as-converted basis together with other convertible preferred stock and common stock. Dividends are noncumulative, and no cash dividends have been declared to date.

Redemption Rights

The Series A, B and C convertible preferred stocks are not currently redeemable. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, the convertible preferred stock is contingently redeemable.

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, subject to the prior rights of the convertible preferred stockholders. 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, 2019, 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,	
	2019	2018
Convertible preferred stock outstanding	24,385,388	16,262,425
Options issued and outstanding	2,516,470	391,098
Options available for future grant	1,550,150	2,528,228
Total common stock reserved	28,452,008	19,181,751

9. Stock-Based Compensation

In April 2017, the Company adopted the 2017 Equity Incentive Plan, or the 2017 Plan. The 2017 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 2017 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.

In October 2019, in connection with the issuance of the Series C convertible preferred stock, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2017 Plan from

3,838,211 shares to 5,249,633 shares. As of December 31, 2019, the Company had 1,550,150 shares available for future grant under the 2017 Plan.

Following the Company's IPO, which was completed on February 4, 2020, and in connection with the effectiveness of the Company's 2020 Equity Incentive Plan, or the 2020 Plan, the 2017 Plan terminated and no further awards will be granted under the 2017 Plan. However, all outstanding awards will continue to be governed by their existing terms. The 2020 plan authorized 2,134,000 shares of common stock available for issuance plus any reserved shares not issued or subject to outstanding grants under the 2017 plan. See Note 13, "Subsequent Events".

Stock Option Activity

The following summarizes option activity under the 2017 Plan (in thousands, except share amounts):

	Number of Options		Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2016	—		$ —	—	$ —
Granted	472,991		$ 0.36		
Exercised	—				
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
Exercisable—December 31, 2019	1,498,001	(1)	$ 3.23	9.41	4,929

(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 estimated fair value of the Company's common stock, as determined by the board of directors, as of December 31, 2019.

The intrinsic value of options exercised for the years ended December 31, 2019 and 2018 was $166,000 and $678,000, respectively. There were no options exercised for the year ended December 31, 2017.

The total grant-date fair value of the options vested during 2019, 2018 and 2017 was $317,000, $130,000 and $25,000, respectively. The weighted-average grant-date fair value of employee options granted during the years ended December 31, 2019, 2018 and 2017 was $2.30, $0.92 and $0.34 per share, respectively.

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,		
	2019	2018	2017
Research and development	$ 351	$ 44	$ 8
General and administrative	473	107	19
Total stock-based compensation expense	$ 824	$ 151	$ 27

As of December 31, 2019, there was $5.6 million of total unrecognized compensation cost related to unvested options that are expected to vest. The cost is expected to be recognized over a weighted-average period of 3.64 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—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.

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,		
	2019	2018	2017
Expected term (in years)	5.1 – 6.6	5.9 – 6.1	6.0
Expected volatility	68.6 – 72.5%	68.2 – 72.4%	84.4 – 84.5%
Risk-free interest rate	1.6 – 2.6%	2.7 – 2.9%	1.9%
Dividend yield	—%	—%	—%

Early Exercise of Employee Options

The terms of the 2017 Plan permit certain option holders to exercise options before their options are vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement. The

shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. Such shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $409,000 and $276,000 as a liability from the early exercise in the accompanying balance sheet as of December 31, 2019 and 2018, respectively. As of December 31, 2019 and 2018, there were $225,000 and $116,000 recorded in accrued liabilities, respectively, and $184,000 and $160,000 recorded in other long-term liabilities, respectively related to shares that were subject to repurchase.

Founder Awards

In August 2016, the Company issued 1,187,738 shares of restricted common stock to founders of which 1,102,903 shares vest under a service condition and 84,835 shares vest under a performance condition. The shares were issued under the terms of the respective restricted stock purchase agreements, or the Stock Purchase Agreement, and unvested shares are subject to repurchase by the Company at the original purchase price per share upon the holder's termination of his relationship with the Company. The restricted shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. One-fourth of the 1,102,903 shares of restricted common stock were vested on the first-anniversary date and the remaining 827,177 shares will vest on a monthly basis thereafter. In July 2018, performance conditions prescribed by the Stock Purchase Agreement were met and 84,835 shares of the restricted common stock were fully vested. During the years ended December 31, 2019, 2018 and 2017, 275,726 shares, 360,560 shares and 413,589 shares of restricted common stock were vested, respectively. As of December 31, 2019, 137,863 shares of restricted stock are unvested.

10. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2019, 2018 and 2017. The Company has incurred net operating losses only in the United States since its inception. The Company has not reflected any benefit of such net operating loss 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,		
	2019	2018	2017
Tax provision at U.S. statutory rate	$ (8,819)	$ (4,043)	$ (1,692)
State income taxes, net of federal benefit	(2,786)	(1,224)	(224)
Research and development tax and other credits	(655)	(265)	(68)
Change in valuation allowance	9,598	4,418	885
Uncertain tax positions	2,604	911	186
Permanent differences	58	219	124
Fair value adjustment	—	(16)	305
Change in federal statutory rate	—	—	484
Provision for income tax	$ —	$ —	$ —

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

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Consolidated Financial Statements

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 11,457	$ 3,606
Intangibles	1,937	1,132
Research and development tax credits	1,092	458
Accruals and reserves	355	117
Right-of-use liability	79	—
Stock-based compensation	62	6
Fixed assets	2	—
Gross deferred tax assets	$ 14,984	$ 5,319
Deferred tax liabilities:		
Right-of-use asset	$ (68)	$ —
Gross deferred tax liabilities	$ (68)	$ —
Net deferred tax assets	$ 14,916	$ 5,319
Less valuation allowance	(14,916)	(5,319)
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 $9.6 million and $4.4 million during the years ended December 31, 2019 and 2018, respectively.

The Company has net operating loss carryforwards for federal and state income tax purposes of approximately $54.6 million and $55.1 million, respectively, as of December 31, 2019. Of the federal net operating losses, $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 $51.0 million of net operating losses generated after December 31, 2017 will be carried forward indefinitely with utilization limited to 80% of taxable income. The state net operating loss carryforwards, if not utilized, will expire beginning in 2036.

As of December 31, 2019, the Company also had federal and California research and development tax credit carryforwards of $2.0 million and $677,000, respectively. The federal research and development tax credit carryforwards will begin to expire in 2037. The California research and development tax credit carryforwards are available indefinitely.

Federal and California tax laws impose significant restrictions on the utilization of net operating loss 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 net operating loss 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,		
	2019	2018	2017
Beginning balance	$ 2,241	$ 441	$ —
Increases related to tax positions taken during a prior year	4	—	—
Increases related to tax positions taken during the current year	4,203	1,800	441
Ending balance	$ 6,448	$ 2,241	$ 441

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 net operating loss carryforwards, all years effectively remain open to income tax examination by the domestic taxing jurisdictions in which the Company files tax returns.

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,		
	2019	2018	2017
Convertible preferred stock on an as-converted basis	24,385,388	16,262,425	3,740,791
Stock options to purchase common stock	2,516,470	391,098	472,991
Early exercised options subject to future vesting	621,053	644,166	—
Restricted stock subject to future vesting	137,863	413,589	774,153
Total	27,660,774	17,711,278	4,987,935

12. Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited financial information on a quarterly basis for 2019 and 2018. 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, 2019				
Total operating expenses	$ 6,952	$ 8,538	$ 14,648	$ 12,994
Other income (expense), 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)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amounts)			
Year Ended December 31, 2018				
Total operating expenses	$ 2,805	$ 3,282	$ 7,695	$ 5,953
Other income (expense), net	84	24	20	352
Net loss	(2,721)	(3,258)	(7,675)	(5,601)
Net loss per share, basic and diluted	$ (2.77)	$ (2.88)	$ (5.72)	$ (3.74)

13. Subsequent Events

Authorized Share Capital

On January 31, 2020, the Company's certificate of incorporation was amended and restated to provide for 65,820,000 authorized shares of common stock with a par value of $0.0001 per share and 48,787,898 authorized shares of preferred stock with a par value of $0.0001 per share.

Initial Public Offering

On January 31, 2020, the Company completed its 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. The Company received gross proceeds of approximately $183.3 million before deducting underwriting discounts, commissions and offering related transaction costs. In connection with the IPO, the Company's outstanding shares of convertible preferred stock were automatically converted into 24,385,388 shares of common stock. The financial statements as of December 31, 2019, including share and per share amounts, do not include the effects of the IPO.

2020 Equity Incentive Plan

In January 2020, the Company's Board of Directors approved the 2020 Equity Incentive Plan, or the 2020 Plan, which became effective upon the completion of the IPO on January 31, 2020.

The 2020 Plan serves as the successor equity incentive plan to the Company's 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, restricted stock awards, stock appreciation rights, restricted stock unit awards, and other stock-based awards, plus any reserved shares not issued or subject to outstanding grants of common stock under the 2017 Plan. In addition, this 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 last day of the immediately preceding fiscal year 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.

2020 Employee Stock Purchase Plan

The Company adopted the 2020 Employee Stock Purchase Plan, or the ESPP, which became effective upon the completion of the IPO on January 31, 2020. The ESPP is designed to allow the Company's eligible employees to purchase shares of the Company's common stock, at semi-annual intervals, with their accumulated payroll deductions. Under the ESPP, participants are offered the option to purchase shares of the Company's common stock at a discount during a series of successive offering periods. The option purchase price will be the lower of 85% of the closing trading price per share of the Company's common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period.

The ESPP is intended to qualify under Section 423 of the U.S Internal Revenue Service Code of 1986. 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 our board of directors; provided, however, no more than 5,265,000 shares of our common stock may be issued under the ESPP.

Coronavirus Outbreak

In March 2020 the World Health Organization declared the global novel coronavirus disease 2019 (COVID-19) outbreak a pandemic. As of March 19, 2020, the Company's operations have not been significantly impacted by the COVID-19 outbreak. 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. The Company does believe that there will be an impact on the clinical development of its product candidates, which may include potential delays, halts or modifications to its ongoing and planned trials.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: March 19, 2020

By: /s/ Todd Franklin Watanabe

Todd Franklin Watanabe
President and Chief Executive 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)	March 19, 2020
/s/ John W. Smither John W. Smither	Chief Financial Officer (Principal Accounting and Financial Officer)	March 19, 2020
/s/ Patrick J. Heron Patrick J. Heron	Director, Chairman	March 19, 2020
/s/ Alexander G. Asam Alexander G. Asam, Ph.D.	Director	March 19, 2020
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri, Ph.D.	Director	March 19, 2020
/s/ Daniel J. Estes Daniel J. Estes, Ph.D.	Director	March 19, 2020
/s/ Jonathan T. Silverstein Jonathan T. Silverstein, J.D.	Director	March 19, 2020
/s/ Ricky Sun Ricky Sun, Ph.D.	Director	March 19, 2020
/s/ Joseph Turner Joseph Turner	Director	March 19, 2020

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 1, 2020, Arcutis Biotherapeutics, Inc. had one class of common stock registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The shares are listed on The Nasdaq Global Select Market under the trading symbol "ARQT."

The following summary describes our common stock and the material provisions of our restated certificate of incorporation, our restated bylaws, the amended and restated investors' rights agreement (the "investors' rights agreement") to which we and certain of our stockholders are parties and of the Delaware General Corporation Law (the "DGCL"). Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our certificate of incorporation, bylaws and investors' rights agreement, filed as exhibits 3.1, 3.2 and 4.2, respectively, to our Annual Report on Form 10-K filed with the Securities Exchange Commission, of which this Exhibit 4.3 is a part. We encourage you to read those documents and the DGCL carefully.

General

The restated certificate of incorporation authorizes 300,000,000 shares of common stock, $0.0001 par value per share.

Common Stock

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation, which means that holders of a majority of the shares of our common stock will be able to elect all of our directors. Our restated certificate of incorporation establishes a classified board of directors, to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Fully Paid and Nonassessable

All outstanding shares of common stock are fully paid and non-assessable.

Registration Rights

Pursuant to the terms of our amended and restated investors' rights agreement certain holders of shares of our common stock are entitled to rights with respect to the registration of these shares under the Securities Act, as described below. We refer to these shares collectively as registrable securities. We generally will pay all expenses, other than underwriting discounts, selling commissions and stock transfer taxes incurred in connection with each of the registrations described above, including the fees and disbursements, not to exceed $50,000, of one counsel for the selling holders.

Beginning 180 days after the completion of our initial public offering, the holders of at least 10% of the then-outstanding registrable securities may make a request to us for the registration under the Securities Act of registrable securities if the aggregate price to the public of the shares offered is at least $10.0 million. We are only required to file two registration statements that are declared effective upon exercise of these demand registration rights.

Any holder or group of holders of at least 10% of then-outstanding registrable securities can request that we register all or part of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least $1.0 million. The stockholders may only require us to effect two registration statements on Form S-3 in a 12-month period.

If we register any of our securities for public sale, holders of then-outstanding registrable securities, or their permitted transferees, will have the right to include their registrable securities in the registration statement.

The registration rights will expire, with respect to any particular holder of these rights, on the earliest to occur of (a) at such time that all of the holder's registrable securities can be sold without limitation in any three-month period without registration in compliance with Rule 144 or a similar exemption under the Securities Act and (b) seven years following the completion of our initial public offering.

Anti-Takeover Provisions

The provisions of the DGCL, our restated certificate of incorporation and our restated bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Restated Certificate of Incorporation and Restated Bylaw Provisions

Our restated certificate of incorporation and our restated bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- *Board of Directors Vacancies. Our restated certificate of incorporation and restated bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.*

- *Classified Board. Our restated certificate of incorporation and restated bylaws provide that our board of directors is classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.*

- *Stockholder Action; Special Meetings of Stockholders. Our restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.*

- *Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.*

- *No Cumulative Voting. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our restated certificate of incorporation and restated bylaws do not provide for cumulative voting.*

- *Directors Removed Only for Cause. Our restated certificate of incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.*

- *Amendment of Charter Provisions. Any amendment of the above expected provisions in our restated certificate of incorporation requires approval by holders of at least two-thirds of our outstanding common stock.*

- *Issuance of Undesignated Preferred Stock. Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by merger, tender offer, proxy contest or other means.*

- *Choice of Forum. Our restated certificate of incorporation provides that, to the fullest extent permitted by law, 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 DGCL, our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. 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 rules 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.*

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company. The transfer agent's address is 1110 Centre Pointe Curve, Suite 101, Mendota Heights, MN 55120-4101.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the 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 March 19, 2020, with respect to the financial statements of Arcutis Biotherapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Los Angeles, California
March 19, 2020

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. for the year ended December 31, 2019;

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

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

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

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

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

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

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

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

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

Date: March 19, 2020

By: /s/ Todd Franklin Watanabe

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

Exhibit 31.2

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

I, John W. Smither, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arcutis Biotherapeutics, Inc. for the year ended December 31, 2019;

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

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

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

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

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

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

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

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

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

Date: March 19, 2020

By: /s/ John W. Smither

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

Exhibit 32.1

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

In connection with the Annual Report of Arcutis Biotherapeutics, Inc. (the "Company") on Form 10-K for the year ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Todd Franklin Watanabe, President, Chief Executive Officer and Director of the Company, and John W. Smither, Chief Financial Officer of the Company, do each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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 result of operations of the Company for the period covered by the Report.

Date: March 19, 2020 By: /s/ Todd Franklin Watanabe

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

Date: March 19, 2020 By: /s/ John W. Smither

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