Filed Pursuant to Rule 424(b)(4)
Registration No. 333-249124

PROSPECTUS

4,000,000 Shares

Common Stock

We are offering 4,000,000 shares of our common stock. Our common stock is listed on the Nasdaq Global Select Market under the symbol "ARQT." On October 1, 2020, the last reported sale price of our common stock as reported on the Nasdaq Global Select Market was $27.62 per share.

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain public company reporting requirements.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 14.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	$ 25.00	$ 100,000,000
Underwriting discounts and commissions(1)	$ 1.50	$ 6,000,000
Proceeds to Arcutis Biotherapeutics, Inc., before expenses	$ 23.50	$ 94,000,000

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

One or more entities managed by OrbiMed, an affiliate of one of our directors, have agreed to purchase $35.0 million of our common stock in a concurrent private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a price per share equal to the public offering, or the concurrent private placement. We will receive the full proceeds and will not pay any underwriting discounts or commissions with respect to the shares that are sold in the concurrent private placement. The concurrent private placement is contingent on the closing of this offering and the satisfaction of certain other customary conditions. However, this offering is not contingent on the consummation of the concurrent private placement.

We have granted the underwriters an option for a period of 30 days to purchase up to 600,000 additional shares of common stock.

The underwriters expect to deliver the shares to purchasers on or about October 6, 2020.

Goldman Sachs & Co. LLC **Cowen** **Guggenheim Securities**
Truist Securities **Cantor**

Prospectus dated October 1, 2020.

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in or incorporated by reference in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in or incorporated by reference in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference filed with the Securities and Exchange Commission, or the SEC, before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statement in another document incorporated by reference having a later date, the statement in the document having the late date modifies or supersedes the earlier statement.

We have not and the underwriters have not taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus and in documents incorporated by reference. This summary is not complete and may not contain all the information you should consider before investing in our common stock. You should read this entire prospectus and the documents incorporated by reference in this prospectus carefully, especially the risks of investing in our common stock discussed under the heading "Risk Factors," and our financial statements and related notes incorporated by reference in this prospectus before making an investment decision. Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus and the documents incorporated by reference in this prospectus to "Arcutis Biotherapeutics," "Arcutis," "the Company," "we," "us" and "our" refer to Arcutis Biotherapeutics, Inc.

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 (topical roflumilast cream), 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 completed enrollment in three Phase 3 studies in plaque psoriasis, with topline data expected in the first quarter of 2021 and a New Drug Application submission anticipated by the end of 2021. We have also completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis patients, reported positive preliminary data for cohort 1, and expect to report topline data for the full study population from both cohorts 1 and 2 in the first quarter of 2021.

We have also completed a Phase 2 study of ARQ-151 in atopic dermatitis, which showed that ARQ-151 could provide symptomatic improvement and a favorable tolerability profile in adults with atopic dermatitis. Following an End of Phase 2 meeting with the FDA in September 2020, we announced our intention to progress ARQ-151 into Phase 3 studies in atopic dermatitis, bypassing our previously planned Phase 2b study in that indication. We anticipate that the Phase 3 program will include at least two pivotal Phase 3 studies of approximately 650 patients each, as well as an open label extension, and will include sufficient patient numbers to meet FDA requirements for a supplemental New Drug Application in atopic dermatitis. We expect to initiate the Phase 3 studies in late 2020 or early 2021.

In addition, we are developing ARQ-154 (topical roflumilast foam), a topical foam formulation of ARQ-151, in seborrheic dermatitis and scalp psoriasis. We have successfully completed a Phase 2 study of ARQ-154 in seborrheic dermatitis, demonstrating potential symptomatic improvement and favorable tolerability of ARQ-154 in this population. We have also completed enrollment of a Phase 2b study in scalp psoriasis, and we expect to report topline data in the fourth quarter of 2020.

In addition, we initiated a Phase 1/2b clinical study of ARQ-252, a potent and highly selective topical Janus kinase type 1, or JAK1, inhibitor for the treatment of hand eczema. We have completed the Phase 1 portion of this clinical study and commenced the Phase 2b portion, and expect topline data in the

second half of 2021. We also plan to initiate a clinical study of ARQ-252 in vitiligo in the second half of 2020. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

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.

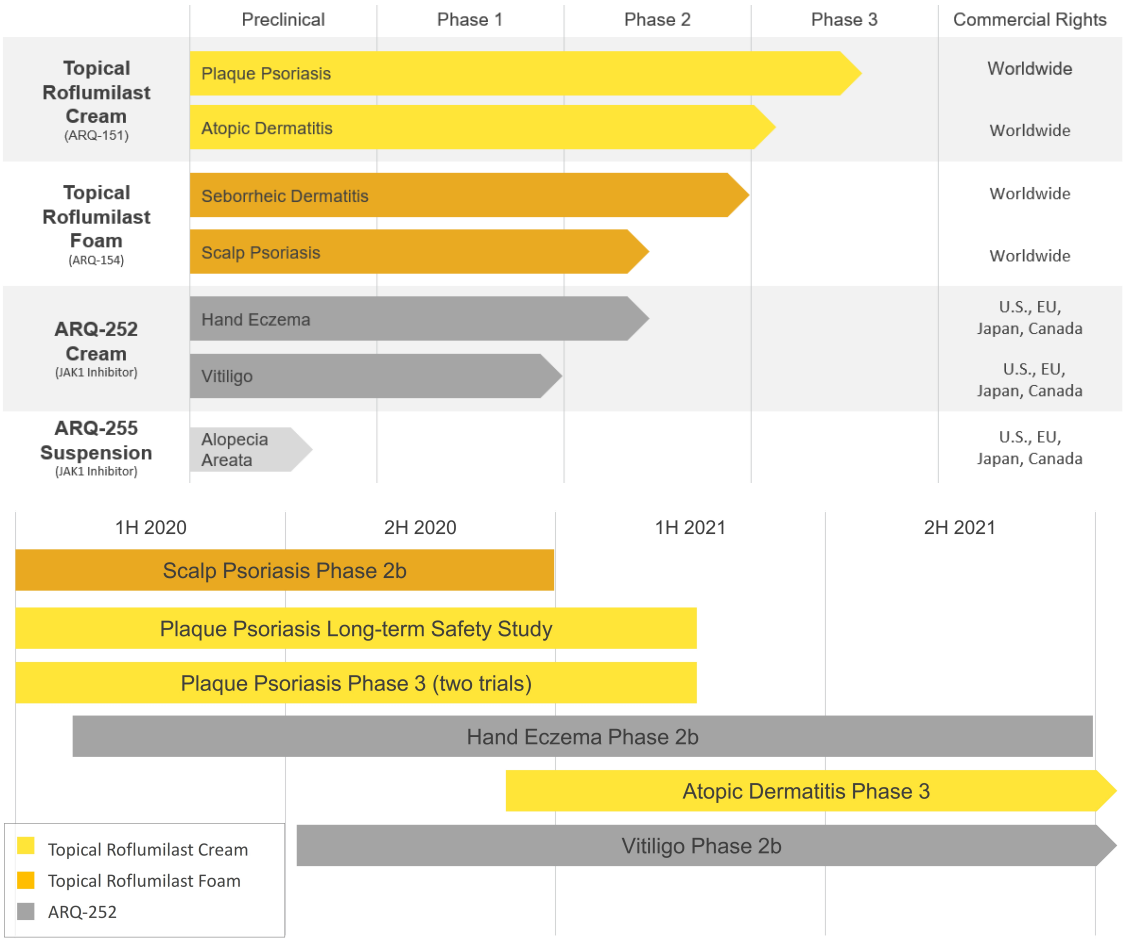
Biologic and systemic therapies are also available, and have shown impressive response rates but are only indicated for the minority of patients with moderate-to-severe forms of disease, are expensive, and often face reimbursement and access restrictions. Use of oral systemic therapies such as methotrexate 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.

Our Pipeline

The following charts summarize our product pipeline, including our lead product candidate, ARQ-151, and our upcoming anticipated milestones:



ARQ-151

Our lead product candidate, ARQ-151, is a topical cream containing roflumilast, a PDE4 inhibitor, that we believe has the potential to offer 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 completed enrollment in three Phase 3 clinical trials in plaque psoriasis and expect to report topline data for all three studies in the first quarter of 2021. In addition, we have completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis, reported positive preliminary data for cohort 1, and expect to report topline data for the full study population from both cohorts 1 and 2 in the first quarter of 2021.

We have also completed a Phase 2 study of ARQ-151 in atopic dermatitis, which showed that ARQ-151 could provide symptomatic improvement and a favorable tolerability profile in adults with atopic dermatitis. Following an End of Phase 2 meeting with the FDA in September 2020, we announced our

intention to progress ARQ-151 into Phase 3 studies in atopic dermatitis, bypassing our previously planned Phase 2b study in that indication. We anticipate that the Phase 3 program will include at least two pivotal Phase 3 studies of approximately 650 patients each, as well an open label extension, and will include sufficient patient numbers to meet FDA requirements for a supplemental New Drug Application in atopic dermatitis. We expect to initiate the Phase 3 studies in late 2020 or early 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.

ARQ-154

We are also developing ARQ-154, a foam formulation of ARQ-151, for treatment of seborrheic dermatitis and scalp psoriasis. 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 designed ARQ-154 as a topical foam version of ARQ-151 to overcome the challenges of delivering topical drugs in hair-bearing areas of the body. We have successfully completed a Phase 2 study of ARQ-154 in seborrheic dermatitis, demonstrating potential symptomatic improvement and favorable tolerability of ARQ-154 in this population. We have also completed enrollment of a Phase 2b study in scalp psoriasis, and we expect to report topline data in the fourth quarter of 2020. We believe that ARQ-154 will 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.

ARQ-252

ARQ-252 is a potent and highly selective topical small molecule inhibitor of JAK1 that we are developing for hand eczema and vitiligo. JAK1 is one of the Janus family of non-receptor protein tyrosine kinases, or JAKs, including JAK1, Janus kinase type 2, or JAK2, Janus kinase type 3, or 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. 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, such as anemia, thrombocytopenia, and neutropenia, associated with JAK2 inhibition.

In January 2018, we executed an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd. of China, or Hengrui, for 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. The Hengrui License Agreement includes composition of matter patents in the United States, and these patents do not begin to expire until 2033. We believe there is the potential to obtain additional protection for ARQ-252 through possible future formulations and other patents.

We initiated a Phase 1/2b study of ARQ-252 in adult patients with hand eczema in the first half of 2020. We have completed the Phase 1 portion of this clinical study and commenced the Phase 2b portion, and expect topline data in the second half of 2021. We also plan to initiate a Phase 2a study of ARQ-252 in vitiligo in the second half of 2020.

ARQ-255

We are also developing ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. We believe that topical JAK inhibitor

therapy for alopecia areata requires the drug to be delivered to the site of the inflammation, 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.

Our Market Opportunity

We believe there are significant market opportunities to capture in each of our addressable markets.

Product Candidate	Mechanism of Action	Formulation	Indication	Primary U.S. Addressable Market Opportunity
ARQ-151	PDE4 Inhibitor	Topical Cream	Psoriasis	Approximately 2.0 million patients treated by dermatologists with topical prescription therapies
			Atopic Dermatitis	Approximately 1.0 million patients treated by dermatologists with topical prescription therapies
ARQ-154	PDE4 Inhibitor	Topical Foam	Seborrheic Dermatitis	Approximately 1.8 million patients treated by dermatologists with topical prescription therapies
			Scalp Psoriasis	Approximately 850,000 patients treated by dermatologists with topical prescription therapies
ARQ-252	JAK1 Inhibitor	Topical Cream	Hand Eczema	Approximately 8.3 million patients
			Vitiligo	Approximately 2.6 million patients
ARQ-255	JAK1 Inhibitor	Topical Suspension	Alopecia Areata	Approximately 6.2 million patients

Our Team

In order to capitalize on our opportunity, we have assembled a management team with deep development, formulation and commercialization expertise for dermatology products. Our management team has held key roles in numerous biotechnology and pharmaceutical companies with a dermatology focus, including Pfizer Inc., Amgen Inc., Gilead Sciences, Inc., Kythera Biopharmaceuticals, Inc., Verrica Pharmaceuticals Inc., and Fougera Pharmaceuticals Inc. Through these roles, our management team was integrally involved in the development, approval and/or commercialization of more than fifty FDA-approved products (including eighteen topical products) such as Enbrel, Jublia, CeraVe, Aczone and Xeljanz. This extensive experience provides us with unique insights and capabilities in dermatology drug development and commercialization.

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 completed enrollment in three Phase 3 clinical

trials and expect to report topline data for all three studies in the first quarter of 2021. In addition, we have completed enrollment in a long-term safety study of ARQ-151 in plaque psoriasis, reported positive preliminary data for cohort 1, and expect to report topline data for the full study population from both cohorts 1 and 2 in the first quarter of 2021. In atopic dermatitis, we have completed a Phase 2 proof of concept study of ARQ-151 and plan to initiate our pivotal Phase 3 program in atopic dermatitis in late 2020 or early 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. We have successfully completed a Phase 2 study of ARQ-154 in seborrheic dermatitis, demonstrating potential symptomatic improvement and favorable tolerability of ARQ-154 in this population. Based on the results of our Phase 2 studies with ARQ-151, we believe ARQ-154 has the potential to offer scalp psoriasis patients symptomatic improvement similar to high-potency steroids, while potentially maintaining a low risk of side effects and favorable tolerability. We have completed enrollment of a Phase 2b study in scalp psoriasis, and we expect to report topline data in the fourth quarter of 2020.
- ***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 initiated a Phase 1/2b study of ARQ-252 in adult patients with hand eczema. We have completed the Phase 1 portion of this clinical study and commenced the Phase 2b portion, and expect topline data in the second half of 2021. We also plan to initiate a Phase 2a study of ARQ-252 in vitiligo in the second half of 2020. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.
- ***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.

Risks Affecting Our Business

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects that you should consider before making a decision to invest in our common stock. These risks are discussed more fully in the section titled “Risk Factors” beginning on page 14 of this prospectus, and include the following:

- We are a late-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and we have incurred significant losses since our inception. We

anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our future operating results to fall below expectations.
- Our business is dependent on the development, regulatory approval and commercialization of our current product candidates.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.
- 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.
- 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.
- We currently rely on single source third-party suppliers 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 suppliers, 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 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.
- 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.
- Epidemic and pandemic diseases, such as COVID-19, or the perception of their effects, could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Recent Developments

On September 29, 2020, we announced positive topline results from our completed Phase 2 study of ARQ-154 in seborrheic dermatitis. The study was a multi-center, multi-national, double-blind, vehicle-controlled study in which 226 adults with moderate-to-severe seborrheic dermatitis received 8 weeks of (1) 0.3% ARQ-154 topical foam once daily, or (2) matching vehicle once daily.

Results from the eight-week treatment period demonstrated statistically significant improvement compared to the matching vehicle on key efficacy endpoints. On the primary efficacy endpoint of

percentage of patients achieving an Investigator's Global Assessment, or IGA, score of "clear" or "almost clear" PLUS a 2-grade improvement from baseline at week 8, 73.8% of patients treated with ARQ-154 achieved "clear" or "almost clear", compared to 40.9% of patients treated with vehicle ($p < 0.0001$). ARQ-154 separated from vehicle with statistical significance on the primary efficacy endpoint and multiple secondary endpoints as early as week 2, the first visit after baseline. ARQ-154 also statistically separated from vehicle in reductions of itch as measured by Worst Itch-Numerical Rating Scale, or WI-NRS, with 64.6% of patients with substantial itching (baseline WI-NRS $\geq$ 4) treated with ARQ-154 experiencing at least a 4-point reduction in their WI-NRS score at week 8, compared to 34.0% of patients treated with vehicle ($p = 0.0007$). Other secondary endpoints included overall assessment of erythema and overall assessment of scaling, which also had positive outcomes.

ARQ-154 was well-tolerated by the patient population, with rates of application site adverse events, treatment-related adverse events and discontinuations due to adverse events low and similar to vehicle. Two out of 154 patients (1.3%) treated with ARQ-154 discontinued the study due to an adverse event, compared to one out of 72 (1.4%) treated with vehicle. Two patients missed the IGA score assessment at week 8 due to concerns arising from COVID-19. As a result, the intent-to-treat and modified intent-to-treat populations differed by two patients, with the results above reflecting the modified intent-to-treat.

Concurrent Private Placement

One or more entities managed by OrbiMed, an affiliate of one of our directors, have agreed to purchase $35.0 million of our common stock in a concurrent private placement exempt from the registration requirements of the Securities Act at a price per share equal to the public offering price in this offering, or the concurrent private placement. We will receive the full proceeds and will not pay any underwriting discounts or commissions with respect to the shares that are sold in the concurrent private placement. The concurrent private placement is contingent on the closing of this offering and the satisfaction of certain other customary conditions. However, this offering is not contingent on the consummation of the concurrent private placement. In connection with the concurrent private placement, we entered into a securities purchase agreement and granted certain customary registration rights pursuant to a registration rights agreement.

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These include, but are not limited to:

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and only two years of selected financial data in this prospectus;
- reduced disclosure obligations regarding executive compensation in this prospectus and in our periodic reports and proxy statements;
- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and the requirement to obtain stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, we are deemed to be a large accelerated filer under rules of the SEC, or we issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting burdens in this prospectus and in the documents incorporated by reference in

this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates.

Corporate Information

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 contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

THE OFFERING

Common stock offered by us	4,000,000 shares
Option to purchase additional shares	We have granted the underwriters an option to purchase up to 600,000 additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Concurrent private placement	One or more entities managed by OrbiMed, an affiliate of one of our directors, have agreed to purchase $35.0 million of our common stock in a concurrent private placement exempt from the registration requirements of the Securities Act at a price per share equal to the public offering price in this offering. Based on the public offering price of $25.00 per share, these entities will purchase 1,400,000 shares. We will receive the full proceeds and will not pay any underwriting discounts or commissions with respect to the shares that are sold in the concurrent private placement. The concurrent private placement is contingent on the closing of this offering and the satisfaction of certain other customary conditions. However, this offering is not contingent on the consummation of the concurrent private placement. In connection with the concurrent private placement, we entered into a securities purchase agreement and granted certain customary registration rights pursuant to a registration rights agreement.
Common stock to be outstanding immediately after this offering and the concurrent private placement	43,090,058 shares (or 43,690,058 shares if the underwriters exercise in full their option to purchase additional shares)
Use of proceeds	We estimate the net proceeds from this offering and the concurrent private placement will be approximately $128.5 million (or approximately $142.6 million if the underwriters exercise their option to purchase additional shares in full), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering and the concurrent private placement, together with our existing cash, cash equivalents and marketable securities, to fund the continued development of our multiple programs, including our ARQ-151, ARQ-154, ARQ-252 and ARQ-255 programs, commercial launch planning and preparation for ARQ-151 in psoriasis, and the remainder for working capital and other general corporate purposes, which may include hiring of additional personnel, capital expenditures and the costs of operating as a public company. See “Use of Proceeds” for more information.

Risk factors	See “Risk Factors” and other information included in or incorporated by reference in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock.
Nasdaq Global Select Market symbol	“ARQT”

The number of shares of common stock to be outstanding after this offering and the concurrent private placement is based on 37,690,058 shares of common stock outstanding as of June 30, 2020, and excludes:

- 3,244,771 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2020, with a weighted-average exercise price of $9.87 per share;
- 130,060 shares of common stock issuable upon the vesting and settlement of restricted stock units, or RSUs, outstanding as of June 30, 2020;
- 440,000 shares of common stock issuable upon the exercise of options outstanding that were granted after June 30, 2020, with a weighted-average exercise price of $26.14 per share;
- 33,500 shares of common stock issuable upon the vesting and settlement of RSUs, that were granted after June 30, 2020;
- 499,235 shares of unvested common stock subject to repurchase by us as of June 30, 2020;
- 2,702,765 shares of common stock that were reserved for future issuance as of June 30, 2020 under our 2020 Equity Incentive Plan, or the 2020 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2020 Plan; and
- 331,138 shares of common stock that were reserved for future issuance as of June 30, 2020 under our 2020 Employee Stock Purchase Plan, or ESPP, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- the issuance of 1,400,000 shares of our common stock to one or more entities managed by OrbiMed upon the closing of the concurrent private placement, based on the public offering price of $25.00 per share;
- no repurchase by us of any shares of unvested common stock subject to repurchase;
- no exercise of the outstanding options or settlement of the outstanding RSUs referred to above; and
- no exercise of the underwriters’ option to purchase additional shares from us.

SUMMARY FINANCIAL DATA

The following tables set forth our summary statements of operations and balance sheet data. The summary statements of operations data for the years ended December 31, 2018 and 2019 have been derived from our audited financial statements and related notes thereto incorporated by reference in this prospectus. We have derived the summary statements of operations data for the six months ended June 30, 2019 and 2020, and the summary balance sheet data as of June 30, 2020, from our unaudited interim condensed financial statements and related notes thereto incorporated by reference in this prospectus. Our unaudited interim condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles on the same basis as our audited annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal, recurring adjustments, that are necessary for the fair statement of our financial position as of June 30, 2020 and our results of operations for the six months ended June 30, 2019 and 2020. The following summary financial data should be read in conjunction with our audited financial statements and unaudited condensed consolidated financial statements incorporated by reference in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period.

	Year Ended December 31,		Six Months Ended June 30,	
(in thousands, except per share data)	2018	2019	2019	2020
			(unaudited)	
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 17,940	$ 36,522	$ 13,417	$ 55,191
General and administrative	1,795	6,610	2,073	9,087
Total operating expenses	19,735	43,132	15,490	64,278
Loss from operations	(19,735)	(43,132)	(15,490)	(64,278)
Other income, net	480	1,136	542	853
Net loss	$ (19,255)	$ (41,996)	$ (14,948)	$ (63,425)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	—	(1)	3	1
Comprehensive loss	$ (19,255)	$ (41,997)	$ (14,945)	$ (63,424)
Net loss per share, basic and diluted	$ (15.53)	$ (22.78)	$ 8.79	$ 2.05
Weighted-average shares used in computing net loss per share, basic and diluted	1,239,689	1,843,213	1,700,549	30,921,866

	As of June 30, 2020	
(in thousands)	Actual	As Adjusted(1)(2)
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 223,975	$ 352,425
Working capital(3)	208,754	337,204
Total assets	231,970	360,420
Total liabilities	23,047	23,047
Total stockholders' equity	208,923	337,373

(1) Gives effect to the issuance and sale by us of 5,400,000 shares of common stock in this offering and the concurrent private placement, based on the public offering price of $25.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(2) We define working capital as current assets less current liabilities. See our audited financial statements and unaudited condensed consolidated financial statements and related notes incorporated by reference in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Before you invest in our common stock, you should understand the high degree of risk involved. You should consider carefully the risk factors discussed below, and all other information contained in or incorporated by reference in this prospectus before making an investment decision. The following risks may adversely impact our business, financial condition and operating results. As a result, the trading price of our common stock could decline and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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

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

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

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

Our net loss for the three and six months ended June 30, 2020 was approximately $35.4 million and $63.4 million, respectively. As of June 30, 2020, we had an accumulated deficit of $129.7 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. We may never achieve profitability and, even if we do, we may not be able to sustain profitability in subsequent periods. We will continue to incur significant research and development and other expenses related to our ongoing operations and the development of our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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

Since our inception, we have invested substantially all of our efforts and financial resources in research and development activities, and we expect to continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates, roflumilast

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

As of June 30, 2020, we had capital resources consisting of cash, cash equivalents and marketable securities of $224.0 million. Based on our planned operations, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations through 2021. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

- the scope, progress, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials, in particular our currently ongoing Phase 3 clinical trials of roflumilast cream in plaque psoriasis, our planned Phase 3 studies of roflumilast cream in atopic dermatitis, our ongoing programs to study roflumilast foam in patients with seborrheic dermatitis and scalp psoriasis, our currently ongoing Phase 1/2b study of ARQ-252 in hand eczema, our planned Phase 2a study of ARQ-252 in vitiligo and our formulation and preclinical efforts for ARQ-255 in alopecia areata;
- suspensions or delays in the enrollment, issues with data collection, or changes to the number of patients we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost of manufacturing our product candidates and any products we commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs, and any discounts or rebates to channel to obtain access
- the cost of building a sales force in anticipation of product commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the timing and amount of milestone payments due to AstraZeneca, Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, or any future collaboration or licensing partners upon the achievement of negotiated milestones;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products, if any.

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

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

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

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

- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates both within and outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements with respect to our product candidates;
- our ability to maintain and enforce our intellectual property position;
- costs related to and outcomes of potential litigation or other disputes in respect of our product candidates and our business;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

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

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

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

Risks Related to Development and Commercialization

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

We currently have no products that are approved for commercial sale. Our current portfolio includes our lead product candidate roflumilast cream, a potent PDE4 inhibitor topical cream for the treatment of plaque psoriasis and atopic dermatitis, and our additional product candidates roflumilast foam, a topical foam formulation of roflumilast cream for the treatment of scalp psoriasis and seborrheic dermatitis,

ARQ-252, a potent and highly selective topical JAK1 inhibitor for the treatment of chronic hand eczema, and ARQ-255, a potential topical treatment for alopecia areata. We currently do not have a drug discovery or research and development effort to discover new product candidates, and we have no intention to develop one. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of these current product candidates. We expect to conduct most of our clinical trials in the United States and Canada, with current limited plans for clinical trials in Australia and the European Union. We currently anticipate seeking regulatory approvals in the United States and Canada, but may in the future be subject to additional foreign regulatory authorities and may out-license our product candidates or approved products, if any, in additional foreign markets. In the future, we may also become dependent on other product candidates that we may acquire or in-license. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate, particularly as a result of the impact of the COVID-19 pandemic, and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our lead product candidates or any future product candidates or approved products, if any;
- the willingness of physicians and patients to utilize or adopt our product candidates;
- the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates to remain in good standing with relevant regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and

- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

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

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

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

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, our Phase 2 proof-of-concept study in atopic dermatitis had a limited number of patients and did not reach statistical significance for the primary endpoint or the secondary endpoint of IGA Success. However, this study did provide evidence that ARQ-151 could provide symptomatic improvement and a favorable tolerability profile in adults with atopic dermatitis and, following an End of Phase 2 meeting with the FDA in September 2020, we announced our intention to progress ARQ-151 into Phase 3 studies in atopic dermatitis, bypassing our previously planned Phase 2b study in that indication. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. For example, we are developing roflumilast foam, including ongoing programs in patients with seborrheic dermatitis and in patients with scalp psoriasis, based on our clinical experience with roflumilast cream in psoriasis. Despite our observations of roflumilast cream in a similar dermatological indication, roflumilast foam may not demonstrate comparable results in scalp psoriasis. In addition, given its different formulation there is a risk that we selected an incorrect dose for roflumilast foam, as the clinical effect of roflumilast foam may differ from roflumilast cream at a similar dosing level or we may observe unexpected side effects not previously observed with roflumilast cream. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- clinical site closures, delays to patient enrollment, subjects discontinuing treatment or follow up visits, issues with data collection, or changes to trial protocols as a result of the COVID-19 pandemic;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

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

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

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

To gain approval to market our product candidates, we must provide the FDA and foreign regulatory authorities with preclinical and clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication applied for in the applicable regulatory filing. Product development is long, expensive and uncertain processes, and delay or failure can occur at any stage of any of our preclinical and clinical development programs. A number of companies in the biotechnology and

pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical or clinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

Our lead product candidate, roflumilast cream, and roflumilast foam, its foam formulation, are currently in clinical development. Our product candidate ARQ-252 is in clinical development for chronic hand eczema and plan to initiate a Phase 2a study of ARQ-252 in vitiligo in the second half of 2020. Additionally, we have formulation and preclinical efforts underway for ARQ-255, an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata. We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize our lead product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions, including pricing approval in the European Union.

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

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

approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

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

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

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

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

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

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

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

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

Certain of our primary and secondary endpoints in our clinical trials, including our currently ongoing Phase 3 clinical trials of roflumilast cream in plaque psoriasis and Phase 2 clinical trial of roflumilast foam in seborrheic dermatitis, involve subjective assessments by physician and patients, which can increase the uncertainty of clinical trial outcomes. For example, one of the secondary endpoints requires patients to report pruritus (itching) as measured by the 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, among others, our Phase 3 clinical trials of roflumilast cream and the inclusion of such data in the product labeling will depend on, but is not limited to, the FDA's review of the following:

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

Further, different results may be achieved depending upon the characteristics of the population enrolled in our studies and which analysis population is used to analyze results. For example, the primary endpoint in our Phase 3 clinical trials of roflumilast cream in plaque psoriasis and our Phase 2 clinical trial of roflumilast foam in seborrheic dermatitis is based on the percentage of patients achieving a score of "clear" or "almost clear" plus at least a 2-grade improvement from baseline on the 5 point IGA scale, referred to as "IGA Success". Success in our clinical trials with these or similar endpoints requires the enrollment of patients with conditions that are severe enough to facilitate a 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 clinical trials will produce the same statistically significant results in "IGA Success", which will serve as the primary endpoint, as our prior clinical trials, and there can be no guarantee that the characteristics of the population enrolled in our clinical trials, including our Phase 3 clinical trials, does not adversely impact the results reported for such trial, any of which could have an adverse effect on our ability to secure regulatory approval for our product candidates.

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

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

Patient enrollment is affected by other factors including:

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

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

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

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

If our product candidates are associated with adverse effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development, institute burdensome monitoring programs, or limit development to more narrow uses or lower or less frequent dosing in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an 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, a Phase 2 study in atopic dermatitis with roflumilast cream, and a Phase 2 study in seborrheic dermatitis with roflumilast foam, and have completed enrollment in a Phase 3 program in plaque psoriasis, which includes three studies comprised of two pivotal studies (DERMIS-1 and DERMIS-2) and an open label extension. We also anticipate commencing pivotal Phase 3 clinical trials of roflumilast cream for the treatment of atopic dermatitis in late 2020 or early 2021. 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. We are finalizing the study designs for our Phase 3 program to evaluate ARQ-151 in patients with atopic dermatitis. While the FDA encouraged us at our End of Phase 2 meeting to generate additional clinical data on the two ARQ-151 doses studied in our Phase 2 study, they also did not raise objections to us proceeding into Phase 3 with a single dose. 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;
- the willingness of patients to pay out-of-pocket for our product candidates, if approved, in the absence of such coverage or sufficient reimbursement;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of any of our product candidates.

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

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

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

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

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

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

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

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

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

Our current sales and marketing organization consists of four employees, including our Chief Commercial Officer. To achieve commercial success for any product for which we obtain marketing approval, we will need to build a significantly more robust sales and marketing organization. We do not currently have any infrastructure for the sales, marketing, or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

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

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

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

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

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

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

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

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

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

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

remedies against us (including by seeking to terminate the relevant agreements), which would harm our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

- develop and commercialize therapies that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our technologies and product;
- obtain required regulatory approvals, including approvals to market our product candidates in ways that are differentiated from existing and future therapies and OTC products and treatments;

- successfully commercialize our product candidates, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapies.

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

Risks Related to Our Business and Operations

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

As of June 30, 2020, we had 49 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our lead product candidates or any future product candidates.

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

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

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

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

Although a substantial amount of our effort will focus on the continued preclinical and clinical testing and potential approval of our current product candidates, a key element of our strategy is to acquire, develop and commercialize a diverse portfolio of product candidates to serve the dermatology market. We do not currently intend to conduct drug discovery or research and development efforts to discover new product candidates, but rather we intend to acquire or in-license rights to existing molecules to develop for

dermatological indications. In addition, while we believe that our strategy allows us to move more rapidly through clinical development and at a potentially lower cost, we may be unable to progress product candidates more quickly or at a lower cost.

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

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

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

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

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

our business could be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

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

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

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

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

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

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

- the inability to commercialize our current or any future product candidates.

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

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

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

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

“large accelerated filer,” our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

In addition, we have begun 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, the ERP system is requiring us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Additionally, during the conversion process, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in implementing or using an ERP system could adversely affect our controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

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

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

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

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

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

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

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

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

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

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws (and other similar non-U.S. laws), if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH, 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 took 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, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these

materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

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

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

We do not have the ability to independently conduct non-clinical studies and clinical trials. We rely on third parties, such as CROs, to conduct preclinical studies and clinical trials of roflumilast cream, roflumilast foam, ARQ-252 and ARQ-255. The third parties with whom we contract for execution of our preclinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. These third parties may also have relationships with other commercial entities, some of which may compete with us. In some cases, these third parties could

terminate their agreements with us without cause. Furthermore, external events such as the COVID-19 pandemic could interfere with some operations of these CROs.

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

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

Risks Related to Intellectual Property

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

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

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

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

and know-how to our processes, methods, and know-how which we consider our trade secrets. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Filing, prosecuting and defending patents on product candidates, including all of the licensed rights under our exclusive supply and license agreements with AstraZeneca and Hengrui, in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing

our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

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

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

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

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

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

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

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

expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

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

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

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

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

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

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us

by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

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

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

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

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would

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

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

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

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

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

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

necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved.

Risks Related to Government Regulation

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

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

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

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

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

they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

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

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

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

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

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

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, customers and patients, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including

how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, (as well as certain other healthcare professionals beginning in 2022) and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members;
- state privacy laws and regulations, such as those of California, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information (for example, in June 2018, California enacted the California Consumer Privacy Act (which went 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.

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

- limited daily trading volume resulting in the lack of a liquid market;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- regulatory, legal or political developments in the United States and foreign countries;
- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;
- the execution of our partnering and manufacturing arrangements;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;

- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the success of, and fluctuations in, the commercial sales any product candidates approved for commercialization in the future;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole, including as a result of market volatility related to global health concerns and, in particular, the extreme volatility experienced during the ongoing COVID-19 pandemic;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- FDA or foreign regulatory actions affecting us or our industry;
- changes in the structure of healthcare payment systems;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;
- the size of our market float;
- the expiration of market standoff or contractual lock-up agreements and future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- changes in accounting principles;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed in this prospectus.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Due to the COVID-19 outbreak, there has been significant stock market exchange volatility, including temporary trading halts. Stock prices of many pharmaceutical companies have fluctuated in a manner

unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

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

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

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

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

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

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

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

public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

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

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

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

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

As of June 30, 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 25.8 million shares of our common stock (including 1.4 million shares to be issued and sold pursuant to the concurrent private placement, based on the public offering price of $25.00 per share) 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.

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

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

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

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

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

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

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

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

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

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

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

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum

provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

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

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

Risks Related to this Offering

We expect that the stock price of our common stock may be volatile or may decline and you may not be able to resell your shares at or above the 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 or legal 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;

- 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 prospectus.

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. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the as adjusted net tangible book value per share. As a result, investors purchasing common stock in this offering will incur immediate dilution of $17.17 per share, based on the public offering price of $25.00 per share, and our as adjusted net tangible book value per share as of June 30, 2020. For more information on the dilution you may suffer as a result of investing in this offering and the concurrent private placement, see the section of this prospectus entitled "Dilution."

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering and the exercise of stock options granted to our employees. The exercise of any of these options would result in additional dilution.

We will have broad discretion in the use of proceeds from this offering and the concurrent private placement and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of proceeds from this offering and the concurrent private placement. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We currently intend to use the net proceeds from this offering and the concurrent private placement, together with our existing cash, cash equivalents and marketable securities, to fund the continued development of our multiple programs, including our ARQ-151, ARQ-154, ARQ-252 and ARQ-255 programs, commercial launch planning and preparation for ARQ-151 in psoriasis, and the remainder for working capital and other general corporate purposes, which may include hiring of additional personnel, capital expenditures and the costs of operating as a public company. Our failure to apply the net proceeds from this offering and the concurrent private placement effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use these net proceeds.

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 Cuts and Jobs Act (as modified by the Coronavirus Aid, Relief, and Economic Security Act), the remaining $51.0 million of federal NOL carryforwards generated after December 31, 2017 will carry forward indefinitely with utilization limited to 80% of taxable income in taxable years starting on or after January 1, 2021. 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.

Under Sections 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 percentage point 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 and development tax credits) to offset its post-change income or taxes may be limited (in addition to those limitations described in the preceding paragraph). A formal study has not been completed to determine if a change in ownership, as defined by Section 382, has occurred. We may have experienced ownership changes in the past (including as a result of our IPO), and we may experience ownership changes in the future and/or subsequent shifts in our stock ownership (some of which may be outside our control), including as a result of this offering and the concurrent private placement. 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 under Section 382, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus contain forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These forward-looking statements include, but are not limited to, 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;
- 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;
- the impact of COVID-19 on our business and operations, including clinical trials, third parties and employees;
- our use of the net proceeds from this offering and the concurrent private placement; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

Forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management’s beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus or incorporated by reference in this prospectus may

turn out to be inaccurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Factors that may cause actual results to differ materially from current expectations include, among other things, those described in the section entitled “Risk Factors” and elsewhere in or incorporated by reference in this prospectus. Potential investors are urged to consider these factors carefully in evaluating these forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

USE OF PROCEEDS

We estimate the net proceeds from this offering and the concurrent private placement will be approximately $128.5 million, or $142.6 million if the underwriters exercise in full their option to purchase additional shares, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering and the concurrent private placement, together with our existing cash, cash equivalents and marketable securities, to fund the continued development of our multiple programs, including our ARQ-151, ARQ-154, ARQ-252 and ARQ-255 programs, commercial launch planning and preparation for ARQ-151 in psoriasis, and the remainder for working capital and other general corporate purposes, which may include hiring of additional personnel, capital expenditures and the costs of operating as a public company.

Based on our planned use of the net proceeds, we estimate such funds, together with our existing cash, cash equivalents and marketable securities, will be sufficient for us to fund our operations into 2022. The expected net proceeds of this offering and the concurrent private placement may not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

The expected use of the net proceeds from the offering and the concurrent private placement represents our intentions based upon our current plans and business conditions. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend on a number of factors, including the success of research and product development efforts, cash generated from future operations and actual expenses to operate our business. We may use a portion of the net proceeds for the acquisition of, or investment in, businesses that complement our business, although we have no present commitments or agreements.

The amounts and timing of our preclinical and clinical expenditures and the extent of preclinical and clinical development may vary significantly depending on numerous factors, including the status, results and timing of our current clinical trials and clinical trials which we may commence in the future, the product approval process with the FDA and foreign regulatory authorities, any new collaborations we may enter into with third parties and any unforeseen cash needs. As a result, we cannot predict with any certainty all of the particular uses for the net proceeds or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering and the concurrent private placement.

Pending the uses described above, we intend to invest the net proceeds from this offering and the concurrent private placement in short term, investment-grade interest-bearing securities such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government.

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.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities, and capitalization as of June 30, 2020:

- on an actual basis; and
- on an as-adjusted basis to give further effect to the issuance and sale of 5,400,000 shares of common stock in this offering and the concurrent private placement based on the public offering price of $25.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information below together with our financial statements and related notes incorporated by reference in this prospectus and the information set forth under the headings “Use of Proceeds” in this prospectus and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report for the year ended December 31, 2019 and our Quarterly Reports on Form 10-Q for the fiscal periods ended March 31, 2020 and June 30, 2020 incorporated by reference in this prospectus.

(in thousands, except for share and per share amounts)	As of June 30, 2020	
	Actual	As Adjusted(1)
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 223,975	$ 352,425
Stockholders’ equity:		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized, actual and as adjusted, no shares issued and outstanding, actual or as adjusted	—	—
Common stock, $0.0001 par value per share; 300,000,000 shares authorized, actual and as adjusted; 38,189,287 shares issued, actual; 37,690,058 shares outstanding, actual; 43,589,287 shares issued and 43,090,058 shares outstanding, as adjusted	3	4
Additional paid-in capital	338,617	467,066
Accumulated other comprehensive income	—	—
Accumulated deficit	(129,697)	(129,697)
Total stockholders’ equity	208,923	337,373
Total capitalization	$ 208,923	$ 337,373

The number of shares of common stock issued and outstanding, actual and as adjusted, in the table above is based on 37,690,058 shares of common stock outstanding as of June 30, 2020, and excludes:

- 3,244,771 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2020, with a weighted-average exercise price of $9.87 per share;
- 130,060 shares of common stock issuable upon the vesting and settlement of RSUs outstanding as of June 30, 2020;
- 440,000 shares of common stock issuable upon the exercise of options outstanding that were granted after June 30, 2020, with a weighted-average exercise price of $26.14 per share;
- 33,500 shares of common stock issuable upon the vesting and settlement of RSUs that were granted after June 30, 2020;
- 499,235 shares of unvested common stock subject to repurchase by us as of June 30, 2020;

- 2,702,765 shares of common stock that were reserved for future issuance as of June 30, 2020 under our 2020 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2020 Plan; and
- 331,138 shares of common stock that were reserved for future issuance as of June 30, 2020 under our ESPP, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share and the as adjusted net tangible book value per share of our common stock immediately after this offering and the concurrent private placement.

Historical net tangible book value (deficit) per share is determined by dividing our total tangible assets (which excludes deferred offering costs) less our total liabilities by the total number of shares of common stock outstanding. Our historical net tangible book value (deficit) as of June 30, 2020 was approximately $208.9 million, or $5.54 per share, based on 37,690,058 shares of common stock outstanding as of that date.

After giving effect to receipt of the net proceeds from our sale of 5,400,000 shares of common stock in this offering and the concurrent private placement at the public offering price of $25.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2020 would have been approximately $337.4 million, or $7.83 per share. This represents an immediate increase in as adjusted net tangible book value of $2.29 per share to our existing stockholders and an immediate dilution of $17.17 per share to new investors participating in this offering.

The following table illustrates this dilution to new investors on a per share basis:

Public offering price per share			$	25.00
Historical net tangible book value per share as of June 30, 2020	$	5.54		
Increase in net tangible book value per share attributable to new investors participating in this offering and the concurrent private placement	$	2.29		
As adjusted net tangible book value per share after this offering and the concurrent private placement				7.83
Dilution per share to new investors participating in this offering and the concurrent private placement			$	17.17

If the underwriters exercise their option in full to purchase additional shares, the pro forma as adjusted net tangible book value per share after this offering would be $8.04 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $0.22 per share and the dilution to new investors in this offering would be $16.96 per share.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 37,690,058 shares of common stock outstanding as of June 30, 2020, and excludes:

- 3,244,771 shares of common stock issuable upon the exercise of options outstanding as of June 30, with a weighted-average exercise price of $9.87 per share;
- 130,060 shares of common stock issuable upon the vesting and settlement of RSUs outstanding as of June 30, 2020;
- 440,000 shares of common stock issuable upon the exercise of options outstanding that were granted after June 30, 2020, with a weighted-average exercise price of $26.14 per share;
- 33,500 shares of common stock issuable upon the vesting and settlement of RSUs that were granted after June 30, 2020;
- 499,235 shares of unvested common stock subject to repurchase by us as of June 30, 2020;

- 2,702,765 shares of common stock that were reserved for future issuance as of June 30, 2020 under our 2020 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2020 Plan; and
- 331,138 shares of common stock that were reserved for future issuance as of June 30, 2020 under our ESPP, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP.

In addition, to the extent that any outstanding options or RSUs described above are exercised, new options are issued, or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

CONCURRENT PRIVATE PLACEMENT

One or more entities managed by OrbiMed, an affiliate of one of our directors, have agreed to purchase $35.0 million of our common stock in a concurrent private placement exempt from the registration requirements of the Securities Act at a price per share equal to the public offering price in this offering. Based on the public offering price of $25.00 per share, these entities will purchase 1,400,000 shares. We will receive the full proceeds and will not pay any underwriting discounts or commissions with respect to the shares that are sold in the concurrent private placement. The concurrent private placement is contingent on the closing of this offering and the satisfaction of certain other customary conditions. However, this offering is not contingent on the consummation of the concurrent private placement. In connection with the concurrent private placement, we entered into a securities purchase agreement and granted certain customary registration rights pursuant to a registration rights agreement.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and certain provisions of our restated certificate of incorporation and restated bylaws are summaries and are qualified in their entirety by reference to the full text of our restated certificate of incorporation and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part. We urge you to read these documents before making any decision to purchase shares of our common stock in this offering.

General

Our authorized capital stock consists of 300,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.0001 par value per share.

Common Stock

As of June 30, 2020, we had outstanding 37,690,058 shares of common stock held of record by approximately 33 stockholders. 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 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, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock

As of June 30, 2020, there were no shares of our preferred stock outstanding.

Under the terms of our restated certificate of incorporation, our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors is also authorized to increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

Options

As of June 30, 2020, options to purchase 3,244,771 shares of common stock, with a weighted-average exercise price of $9.87 per share, were outstanding under our equity compensation plans.

Restricted Stock Units

As of June 30, 2020, we had 130,060 shares of common stock issuable upon the vesting and settlement of outstanding RSUs.

Registration rights

Pursuant to the terms of our amended and restated investors' rights agreement, or the Investor Rights Agreement, the holders of up to 24,385,388 shares of our common stock or their transferees have rights with respect to the registration of their shares under the Securities Act, as described below. We refer to these shares collectively as registrable securities. In addition, in connection with the concurrent private placement, we entered into a securities purchase agreement to issue and sell $35.0 million of our common stock and granted certain customary registration rights pursuant to a registration rights agreement. Based on the public offering price of $25.00 per share, the purchasers of 1,400,000 shares of our common stock in the concurrent private placement will have rights with respect to the registration of their shares under the Securities Act.

Form S-1 Registration Rights

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. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would materially interfere with a corporate transaction, require premature disclosure of confidential information or render us unable to comply with the Securities Act or Exchange Act, we have the right to postpone such registration, not more than once in any 12-month period, for a period of up to 90 days.

Form S-3 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 any 12-month period. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. Additionally, if we determine that it would materially interfere with a corporate transaction, require premature disclosure of confidential information or render us unable to comply with the Securities Act or Exchange Act, we have the right to postpone such registration, not more than once in any 12-month period, for a period of up to 90 days.

Piggyback Registration Rights

In connection with this offering, certain holders of then-outstanding registrable securities were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. If we register any of our securities for public sale, holders of then-outstanding registrable securities are entitled to certain “piggyback” registration rights allowing the holders to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to certain registrations, including related to any of our employee benefit plans, the offer and sale of debt securities, or an SEC Rule 145 transaction, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, we and the underwriters have the right, subject to specified conditions, to limit the number of shares such holders may include.

Expenses of Registration Rights

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.

Expiration of Registration Rights

The registration rights described above will expire, with respect to any particular holder of these rights, on the earliest to occur of (a) the closing of a deemed liquidation event, as defined in our restated certificate of incorporation, (b) 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 (c) seven years following the completion of our initial public offering.

Anti-takeover provisions

The provisions of Delaware General Corporation Law, or 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 provisions in our restated certificate of incorporation require 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.

The Nasdaq Global Select Market Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol "ARQT."

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of our common stock, including shares issued upon exercise of outstanding options or warrants, in the public market following this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market after consummation of this offering due to contractual and legal restrictions on resale described below.

Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Based on the number of shares of our common stock outstanding as of June 30, 2020, upon the completion of this offering and the concurrent private placement and assuming (1) no exercise of the underwriters' option to purchase additional shares of common stock and (2) no exercise of any of our other outstanding options, we will have outstanding an aggregate of 43,090,058 shares of common stock.

All of the shares of common stock sold in this offering, and any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act. Certain of the remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering are or will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

Lock-up Agreements and Market Stand-off Provisions

In connection with this offering, we, and our directors, executive officers and certain of our stockholders have agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 90 days following the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC and Cowen and Company, LLC.

Subject to certain limitations, certain of our employees, including our executive officers, and/or directors have entered into, and may enter into, written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act.

Following the lock-up periods set forth in the market stand-off and lock-up agreements described above, and assuming that Goldman Sachs & Co. LLC and Cowen and Company, LLC do not release any parties from the lock-up agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act, for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior

owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreements referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than "affiliates," then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our "affiliates," as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 430,900 shares of common stock immediately after this offering and the concurrent private placement; or
- the average weekly trading volume of our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our "affiliates" or persons selling shares on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally provides that a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is not deemed to have been one of our affiliates at any time during the preceding 90 days may sell such shares (to the extent such shares are not subject to a lock-up agreement) in reliance upon Rule 144 without complying with the current public information or holding period conditions of Rule 144. Rule 701 also provides that a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is deemed to have been one of our affiliates during the preceding 90 days may sell such shares under Rule 144 without complying with the holding period condition of Rule 144 (subject to any applicable lock-up agreement).

Registration Rights

The holders of approximately 25,785,388 shares of our common stock (including 1,400,000 shares to be issued and sold pursuant to the concurrent private placement, based on the public offering price of $25.00 per share), or their transferees, will, subject to the lock-up agreements referred to above, be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. For a description of these registration rights, see "Description of Capital Stock—Registration Rights." If the offer and sale of these shares are registered, they will be freely tradable without restriction under the Securities Act. In connection with the concurrent private placement, we entered into a securities purchase agreement and granted certain customary registration rights pursuant to a registration rights agreement.

Stock Plans

We have filed with the SEC a registration statement under the Securities Act covering the shares of common stock reserved for issuance under our equity compensation plans. Accordingly, shares registered under such registration statement are available for sale in the open market, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

(a) an individual who is a citizen or resident of the United States;

(b) a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;

(c) an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

(d) a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend Policy," we do not anticipate paying any cash dividends on our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below regarding effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable tax treaties.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively

connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below regarding backup withholding, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

(a) the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);

(b) the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or

(c) our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by certain U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the Non-U.S. Holder certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above or the Non-U.S. Holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated

relationships with the United States generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock beginning on January 1, 2019, Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Cowen and Company, LLC and Guggenheim Securities, LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	1,400,000
Cowen and Company, LLC	1,040,000
Guggenheim Securities, LLC	840,000
Truist Securities, Inc.	400,000
Cantor Fitzgerald & Co.	320,000
Total	4,000,000

The underwriters will be committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 600,000 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days from the date of this prospectus. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares from us.

	No Exercise	Full Exercise
Per Share	$ 1.50	$ 1.50
Total	$ 6,000,000	$ 6,900,000

We estimate that our total out of pocket expenses for this offering, excluding the underwriting discounts and commissions, and the concurrent private placement will be approximately $550,000. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $35,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

Shares sold by the underwriters to the public will initially be offered at the public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $0.90 per share from the public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We have agreed that, subject to certain limited exceptions, we will not (i) offer, sell, contract to sell, pledge, lend, grant any option to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, or file with or confidentially submit to the SEC a registration statement under the Securities Act relating to, any of our securities that are substantially similar to our shares of common stock, including but not limited to any options or warrants to purchase shares of common stock or any securities that are convertible into or exchangeable for, or that represent the right to receive, shares of common stock or any such substantially similar securities, or publicly disclose the intention to make any

offer, sale, pledge, loan, disposition, confidential submission or filing or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our shares of common stock or any such other securities (in either case, regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of Goldman Sachs & Co. LLC and Cowen and Company, LLC for a period through and including the date that is 90 days after the date of this prospectus.

Our directors, executive officers and certain of our stockholders have entered into lock-up agreements with the underwriters, pursuant to which each of these persons or entities, subject to certain limited exceptions, for a period through and including the date that is 90 days after the date of this prospectus, agree that they will not, and shall not, without the prior written consent of Goldman Sachs & Co. LLC and Cowen and Company, LLC, cause or direct any of their respective affiliates to, (i) offer, sell, contract to sell, pledge, grant any option to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock, or any options or warrants to purchase any shares of common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of common stock, whether now owned or hereafter acquired, owned directly by each such person or entity (including holding as a custodian) or with respect to which such person or entity has beneficial ownership within the rules and regulations of the SEC, (ii) engage in any hedging or other transaction or arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition (whether by such person or entity or someone other than such person or entity), or transfer of any of the economic consequences of ownership, in whole or in part, directly or indirectly, of the securities owned by such person or entity, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of common stock or other securities, in cash or otherwise, or (iii) otherwise publicly announce any intention to engage in or cause any action or activity described in clause (i) above or transaction or arrangement described in clause (ii) above.

Our common stock is listed on The Nasdaq Global Select Market under the symbol “ARQT.”

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses. Certain of the underwriters also served as underwriters in our initial public offering in February 2020.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to Prospective Investors in European Economic Area and United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each, a “Relevant State”), no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Member State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in United Kingdom

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (as amended, the "FSMA")) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the company; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Notice to Prospective Investors in Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority ("FINMA") as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended ("CISA"), and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licensable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The securities may solely be offered to "qualified investors," as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended ("CISO"), such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

Notice to Prospective Investors in Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Hong Kong

The securities may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) ("Securities and Futures Ordinance"), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in

Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Notice to Prospective Investors in Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728—1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed Investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law,

5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Latham & Watkins LLP, Menlo Park, California. Certain legal matters relating to the offering will be passed upon for the underwriters by Cooley LLP, San Francisco, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits filed therewith. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete, please see the copy of the contract or document that has been filed for the complete contents of that contract or document. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

We also maintain a website at www.arcutis.com. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider information on our website to be part of this prospectus.

You may also request a copy of these filings, at no cost to you, by writing or telephoning us at the following address:

Arcutis Biotherapeutics, Inc.
Attn: VP Investor Relations & Corporate Communications
2495 Townsgate Road, Suite 110
Westlake Village, California 91361
Telephone: (805) 418-5006

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 19, 2020;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020, filed with the SEC on May 12, 2020 and August 11, 2020, respectively;
- our Current Reports on Form 8-K, filed with the SEC, on April 27, 2020, April 29, 2020, July 29, 2020, July 31, 2020, September 9, 2020, September 18, 2020 and September 29, 2020; and
- the description of our securities registered pursuant to Section 12 of the Exchange Act contained in Exhibit 4.3 to our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 19, 2020, including any amendment or report filed for the purpose of updating such description.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Arcutis Biotherapeutics, Inc., Attn: VP Investor Relations & Corporate Communications, 2495 Townsgate Road, Suite 110, Westlake Village, CA 91361; Telephone: (805) 418-5006; E-mail: information@arcutis.com.

You also may access these filings on our website at www.arcutis.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

4,000,000 Shares

Arcutis Biotherapeutics, Inc.

Common Stock

PROSPECTUS

Goldman Sachs & Co. LLC **Cowen** **Guggenheim Securities**
Truist Securities **Cantor**

Prospectus dated October 1, 2020