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2024 ANNUAL REPORT

ARCUTIS BIOTHERAPEUTICS



Dear Arcutis Stockholders

In 2024, Arcutis continued a relentless focus on our goal of becoming a leading innovation-driven immunology company and improving the lives of people struggling with skin diseases. Most of our efforts centered on advancing our "pipeline in a product", ZORYVE® (roflumilast). We ended the year with three FDA-approved dermatology indications, creating a unique portfolio in dermatology with multiple formulations and indications and driving significant revenue growth. We also filed for a fourth indication, and another label expansion, both with potential 2025 approvals. ZORYVE now addresses the significant unmet needs of over 17 million patients.

Based on its rapid and robust efficacy and favorable tolerability, ZORYVE has quickly become the number one prescribed branded topical agent across our combined three approved indications. In January 2024, we launched ZORYVE (roflumilast) topical foam 0.3% for seborrheic dermatitis down to age 9, which quickly became the new standard of care for prescribers and patients in this indication. In July, we received approval for and launched ZORYVE (roflumilast) cream 0.15% for atopic dermatitis in adults and children down to age 6. Concurrent with this launch, we expanded our sales organization, thereby increasing our share of voice. We also entered into a partnership with Kowa, adding a 200+ person sales force to promote ZORYVE in primary care and pediatric practices. This provides a significant new growth opportunity by tapping into the 8.6 million individuals treated outside of dermatology for our targeted conditions.

On the regulatory front, we submitted a supplemental New Drug Application (sNDA) for ZORYVE foam 0.3% for the treatment of adults and adolescents ages 12 and over with scalp and body psoriasis, with an FDA target action date in May. We also submitted an sNDA for ZORYVE cream 0.05% for the treatment of children ages 2 to 5 with atopic dermatitis, with a target action date in October. Positive results from two pivotal Phase 3 studies (INTEGUMENT-1 and -2) evaluating the efficacy and safety of ZORYVE cream 0.15% were published in the Journal of American Medical Association Dermatology in September.

We expect to sustain ZORYVE's strong growth as we drive the conversion from topical steroids, garner additional indications, expand into primary care and pediatrics, and continue to gain favorable commercial and government insurance coverage.

In parallel, we progressed our pipeline, completing enrollment of the Phase 1 study of our novel topical JAK inhibitor ARQ-255 in alopecia areata, with results expected in the first half of 2025, and we made substantial progress on advancing ARQ-234, our biologic treatment option for atopic dermatitis, into the clinic, with an Investigational New Drug application expected during 2025.

Globally, Arcutis Canada, Inc., received regulatory approval from Health Canada for ZORYVE topical foam 0.3% for the treatment of seborrheic dermatitis in patients 9 years of age and older, and launched that product late in the year. We also entered into a strategic collaboration and licensing agreement for topical roflumilast in Japan with Sato Pharmaceutical Co., Ltd., introducing a novel non-steroidal topical option for millions of Japanese patients with inflammatory skin diseases. Additionally, our partner Huadong made considerable progress on the development of topical roflumilast in China, including initiating their first clinical trial.

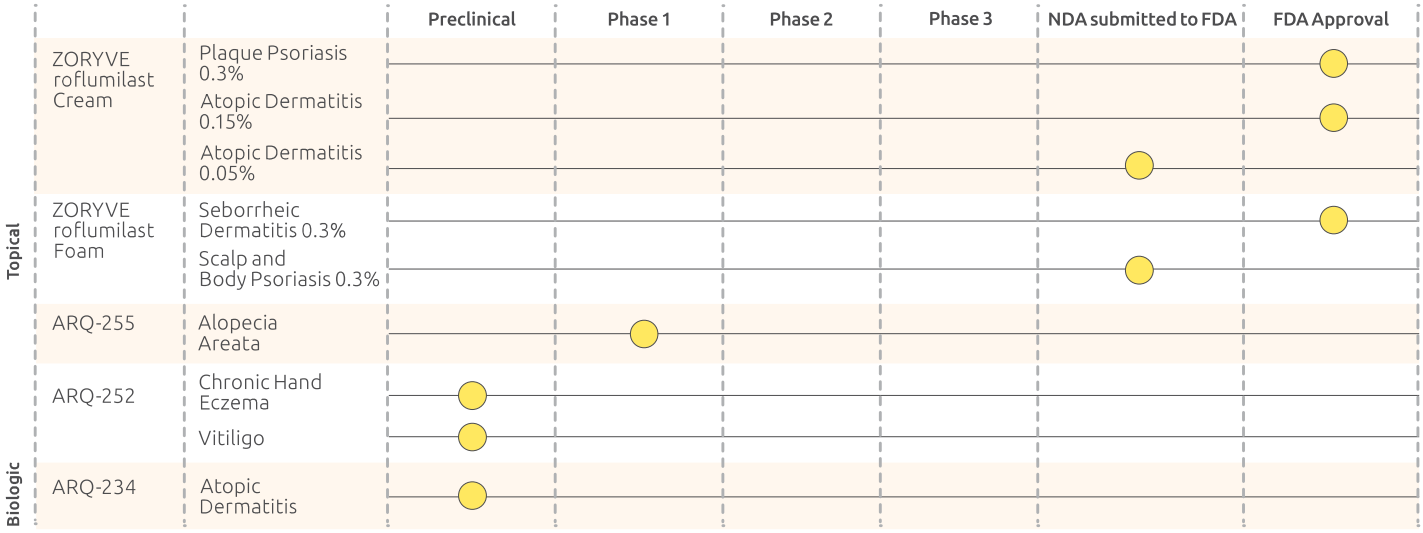
We had a remarkable 2024, with strong execution that unlocked significant shareholder value while positively impacting countless people afflicted by chronic, debilitating dermatological diseases. We expect further momentum in 2025, as we continue to grow ZORYVE, drive the shift from topical steroids, and advance our pipeline; all while continuing to strengthen the financial position of the business.

On behalf of Arcutis, its Board of Directors, and employees, we thank you for your continued support and look forward to updating you on our 2025 accomplishments and progress.



Frank Watanabe – President and Chief Executive Officer

Our growing portfolio and robust pipeline



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For transition period from ____ to ____

Commission File Number: 001-39186

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $984,420,698, based on the closing price of the registrant's common stock as reported on The Nasdaq Global Select Market.

The number of shares of the registrant's Common Stock outstanding as of February 19, 2025 was 118,638,235.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Proxy Statement for the registrant's 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K to the extent stated herein. The Proxy Statement will be filed within 120 days of the registrant's fiscal year ended December 31, 2024.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business" contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect", and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- the success, cost, and timing of our plans to develop and commercialize immuno-dermatology drugs, including our current products, ZORYVE® (roflumilast) cream 0.3% (ZORYVE cream 0.3%), ZORYVE® topical foam (ZORYVE foam), ARQ-234, ARQ-252, and ARQ-255 for indications including plaque psoriasis, atopic dermatitis, scalp psoriasis, seborrheic dermatitis, hand eczema, vitiligo, and alopecia areata;
- our ability to continue as a going concern and to obtain funding for our operations, including funding necessary to complete further development and commercialization of our products and product candidates;
- our ability to satisfy the conditions, covenants, and obligations under our amended loan and security agreement with SLR Investment Corp.;
- the timing of and our ability to obtain and maintain regulatory approvals;
- future agreements, if any, with third parties in connection with the commercialization of our products and product candidates, if approved for commercial uses;
- 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 products and product candidates, if approved for commercial uses;
- the potential market size and the size of the patient populations for our products and product candidates, if approved for commercial uses;
- the potential U.S. and Canadian market sales for our products and 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 products and product candidates; and
- our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing.

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

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

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

Summary of Risk Factors

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

- We are a commercial-stage biopharmaceutical company with three products approved for commercial sale. We have incurred significant losses since our inception, and could continue to incur losses, which, together with our limited history as a commercial-stage company, makes it difficult to assess our future viability;
- Due to the recent commercialization of products approved for commercial sale, as well as our development strategy and continued development of our pipeline of product candidates, our capital requirements are difficult to predict and may change. We may require substantial additional financing to achieve our goals, and a failure to obtain this capital if or when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate certain operations or efforts;
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our future operating results to fall below expectations;
- Our estimated market opportunities are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited;
- The terms of our loan and security agreement require us to meet certain operating and financial covenants, and place certain restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business;
- The sales, marketing, and distribution of ZORYVE or any future approved products may be unsuccessful or less successful than anticipated;
- Our business is dependent on the successful commercialization of ZORYVE and the development, regulatory approval, and commercialization of our product candidates;
- Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payers, or others in the medical community necessary for commercial success;
- If we are unable to achieve and maintain third-party payer coverage and adequate levels of reimbursement for ZORYVE or 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;
- 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 prevent or delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business, and our results of operations;
- Topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- Certain of the endpoints in our planned clinical trials rely on a subjective assessment of the effect of the product candidate in the subject by either the physician or subject, and may prove difficult to meet in subjects with more severe disease, which exposes us to a variety of risks for the successful completion of our clinical trials;
- Enrollment and retention of subjects in clinical trials is expensive and time-consuming and may result in additional costs and delays in our product development activities, or in the failure of such activities;

- Serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs, or necessitate the abandonment or limitation of the development of some of our product candidates;
- We may need to increase the size of our organization, and we may experience difficulties in executing our growth strategy, managing any growth, and retaining talent;
- 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;
- 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;
- Any collaboration arrangements that we have entered into or may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize future product candidates;
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of ZORYVE or our current or future product candidates;
- We rely on third-party manufacturers to manufacture nonclinical, clinical, and commercial supplies of ZORYVE and our product candidates. The loss of these manufacturers or their sub-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;
- If our third-party manufacturers fail to comply with manufacturing or other regulations, our financial results and financial condition will be adversely affected;
- We rely on third parties to conduct our nonclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates;
- Risks related to our intellectual property could materially adversely impact our business, competitive position, financial condition, and results of operations;
- Risks related to government regulation of our industry and required approvals could materially adversely impact our business, competitive position, financial condition, and results of operations; and
- Future litigation could have a material adverse effect on our business and results of operations.

TRADEMARKS

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

MARKET AND INDUSTRY DATA

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

sole responsibilities of us and such third-party. In no way shall any data appearing in the DR Materials amount to any form of prediction of future events or circumstances and no such reliance may be inferred or implied.

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

Part I

Item 1. BUSINESS

Overview

We are a commercial-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. Our current portfolio is comprised of highly differentiated topical and systemic treatments with significant potential to treat immune-mediated dermatological diseases and conditions. We believe we have built a leading platform for dermatologic product development and commercialization. Our strategy is to focus on validated biological targets, and to use our drug development platform and deep dermatology expertise to develop and commercialize differentiated products that have the potential to address the major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly advance our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

We launched our lead product, ZORYVE® (roflumilast) cream 0.3% (ZORYVE cream 0.3%) in August 2022 after obtaining our initial U.S. Food and Drug Administration (FDA) approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (e.g. groin or axillae), in individuals 12 years of age or older. ZORYVE cream 0.3% is a once-daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor. ZORYVE cream 0.3% is approved for once-daily treatment of mild, moderate, and severe plaque psoriasis with no limitations on location or duration of use. In October 2023, we received FDA approval for an expanded indication in plaque psoriasis down to 6 years of age. We are currently working with the FDA to potentially further expand this indication in plaque psoriasis down to 2 years of age following the generation of additional clinical data. In April 2023, we had our first commercial launch outside of the United States following Health Canada approval of ZORYVE cream 0.3% for the treatment of plaque psoriasis in individuals 12 years or age or older.

In December 2023, we received FDA approval for ZORYVE® (roflumilast) topical foam 0.3% (ZORYVE foam) for the treatment of seborrheic dermatitis in individuals aged 9 years and older, with no limitation on severity, location, or duration of use. ZORYVE foam is a once-daily steroid-free foam and, as a PDE4 inhibitor, is the first drug approved for the treatment of seborrheic dermatitis with a new mechanism of action in over two decades. ZORYVE foam became commercially available in the United States in late January 2024, and was approved by Health Canada in October 2024 and became commercially available in Canada in December 2024.

In addition to the approval of ZORYVE cream 0.3% for plaque psoriasis and ZORYVE foam for seborrheic dermatitis, we also received FDA approval for and commercially launched ZORYVE (roflumilast) cream 0.15% (ZORYVE cream 0.15%), (collectively, ZORYVE), in July 2024 for the treatment of mild to moderate atopic dermatitis in adults and pediatric patients 6 years of age and older, with no limitation on location, body surface area treated, concomitant use, or duration of use specified in the approved labelling. ZORYVE cream 0.15% is a once-daily, steroid-free cream that provides rapid disease clearance and significant reduction in itch and has been specifically developed to be a treatment option for long-term disease control. We have also completed a Phase 3 trial of ZORYVE cream 0.05% in pediatric patients 2 to 5 years of age with mild to moderate atopic dermatitis (INTEGUMENT-PED). Based on the positive results from the INTEGUMENT-PED study, and given our recent approval of ZORYVE cream 0.15% for the treatment of mild to moderate atopic dermatitis in individuals 6 years of age or older, we submitted a supplemental new drug application (sNDA) for topical ZORYVE cream 0.05% for children 2 to 5 years of age in December 2024. We conducted INTEGUMENT-OLE, an open label extension study of the long-term safety of ZORYVE cream 0.15% in subjects 6 years of age or older and ZORYVE cream 0.05% in

subjects between the ages 2 and 5 years, for which we reported positive results in September 2023 and August 2024, respectively.

Beyond seborrheic dermatitis, we are also developing ZORYVE foam for scalp and body psoriasis and have successfully completed our Phase 2b and pivotal Phase 3 clinical trials. We announced positive topline data in September 2022, with ZORYVE foam showing rapid disease clearance and significant reduction in itch. In the pivotal Phase 3 ARRECTOR study, at Week 8, 66% of individuals treated with ZORYVE foam achieved the co-primary efficacy endpoint of Scalp IGA Success, defined as a Scalp IGA score of “clear” or “almost clear” plus a 2-point improvement, and 46% of patients achieved the co-primary efficacy endpoint of Body IGA Success, defined as a Body IGA score of "clear" or "almost clear" plus a 2-point improvement. In addition, individuals treated with ZORYVE foam reported reductions in itch from baseline within 24 hours of first application. Based on the ARRECTOR results and a Phase 2b study, we submitted an sNDA to the FDA for a label expansion to include scalp and body psoriasis in adults and adolescents ages 12 and over, which was recently accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date in May 2025.

In July 2024, we entered into a co-promotion agreement with Kowa Pharmaceuticals, Inc. (Kowa) to leverage Kowa's primary care sales force to exclusively market and promote ZORYVE in the United States to primary care practitioners and pediatricians for all FDA-approved indications until at least July 2029. Under the terms of the agreement, Kowa will receive a commission from net sales attributed to Kowa. Promotion of ZORYVE in primary care and pediatrics under the Kowa agreement began in late September 2024.

In addition to ZORYVE, we are developing ARQ-255, a deep-penetrating topical formulation of ivarmacitinib, a potent and highly selective topical Janus kinase type 1 (JAK1) inhibitor, designed to preferentially deliver the drug deep into the hair follicle, the site of inflammation in alopecia areata, in order to potentially develop the first topical treatment for this disease. We completed enrollment in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata and expect data in the first half of 2025.

In September 2022, we acquired Ducentis BioTherapeutics LTD (Ducentis) and its lead asset, DS-234 (now ARQ-234), a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 Receptor (CD200R). Currently in the preclinical stage, we plan to develop ARQ-234 in atopic dermatitis, where we believe it could be a potentially highly complementary biologic treatment option to ZORYVE cream in that indication, if approved. ARQ-234 could potentially be used to treat other inflammatory conditions as well. We are working towards submitting an Investigational New Drug (IND) application during 2025.

Dermatological diseases such as psoriasis, atopic dermatitis, seborrheic dermatitis, and alopecia areata affect hundreds of millions of people worldwide each year, impacting their quality of life, and physical, functional, and emotional well-being. There are many approved treatments for these conditions, but a large opportunity remains due to issues with existing treatments. Topical treatments are used for nearly all patients, but existing topicals are limited by one or more of the following: modest response rates, side effects, patient adherence, application site restrictions, and limits on duration of therapy. Topical corticosteroids (TCS), are commonly used as the first-line therapy for the treatment of inflammatory skin conditions such as psoriasis, atopic dermatitis, and seborrheic dermatitis. While many patients see improvements, long-term TCS treatment carries the risk of a variety of significant side effects. As a result, TCS are typically used intermittently for brief periods, which can lead to disease flares when patients stop TCS therapy. In psoriasis, vitamin D analogs are also used, but have lower response rates than TCS and are frequently irritating. Topical tapinarof was approved in May 2022 for the treatment of adults with plaque psoriasis and in December 2024 for adults and children with atopic dermatitis, but this non-steroidal agent also carries significant application site reactions. In atopic dermatitis, topical calcineurin inhibitors, or TCIs, and crisaborole (Eucrisa®), a topical non-steroidal PDE4 inhibitor, are used, but have lower response rates than TCS and are associated with application site burning. TCIs also have a boxed warning for cancer risk. Topical ruxolitinib (Opzelura®) was approved for the treatment of atopic dermatitis in September 2021, but carries an extensive boxed warning for numerous severe side effects, and is limited to short-term, intermittent use after failure of other treatments. In seborrheic dermatitis, in addition to TCS, topical antifungals are commonly used, but have limited efficacy.

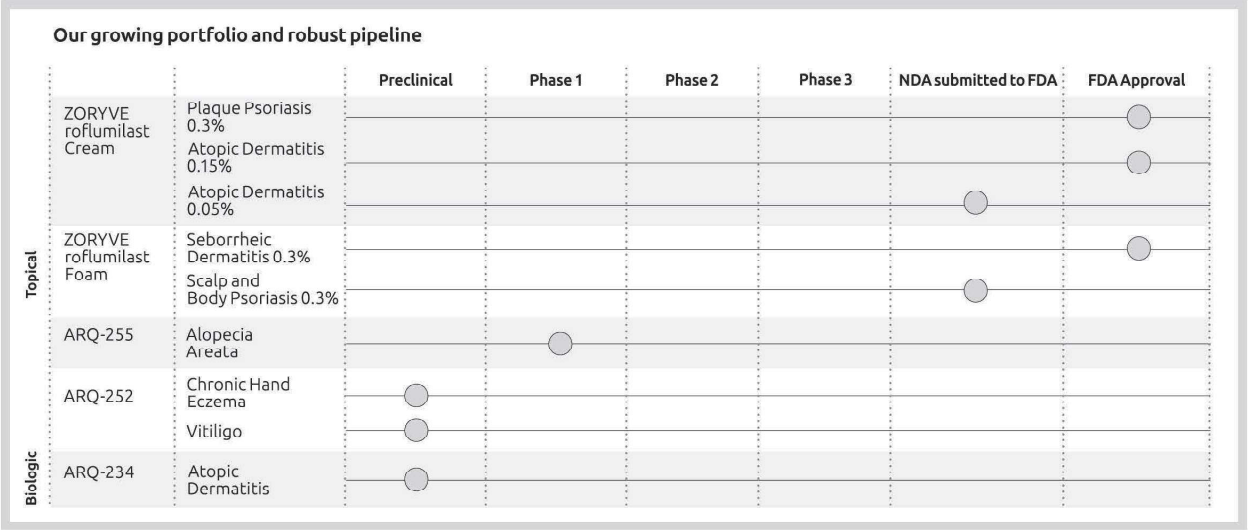
Biologic and systemic therapies are also available for some diseases, but are typically indicated for a small percentage of the affected population. Biologics for psoriasis have shown impressive response rates but are only indicated for the minority of patients with moderate-to-severe forms of disease,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

to continue to advance the standard of care for patients, for example with regard to response rates and dosing frequency.

Given the limitations associated with existing treatments, we believe patients with inflammatory skin conditions and their dermatologists are dissatisfied with their current treatment options. We believe that there is a significant opportunity to leverage developments in other fields of medicine, particularly inflammation and immunology, to address the significant need for effective chronic treatments in immuno-dermatology. Our primary focus since our founding has been to address patients' significant need for innovative topical treatments that directly target molecular mediators of disease, have the potential to show significant symptomatic improvement, maintain a low risk of toxicity or side effects, and are suitable for chronic use on all areas of the body. Based on market research and our internal estimates, we estimate there is an overall actively prescription treated patient market of approximately 17.0 million patients in the United States that are treated with topical therapies for plaque psoriasis, seborrheic dermatitis, and atopic dermatitis in dermatology offices (approximately 8.4 million) and outside dermatology (approximately 8.6 million). Of the patients that are treated in dermatology offices, we estimate that approximately 3.7 million of these patients are covered by Medicare or Medicaid, while approximately 4.7 million are covered by private payers. Patients that are treated outside of dermatology offices are primarily treated by primary care providers and pediatricians, and the ratio of commercial to government insurance is similar.

Our Portfolio and Pipeline

The following chart summarizes our product portfolio and pipeline:



Our Strategy

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

Key elements of our strategy include:

- ***Commercialize ZORYVE cream 0.3% for the treatment of patients with plaque psoriasis and ZORYVE cream 0.15% for the treatment of patients with atopic dermatitis.*** We commercially launched ZORYVE cream in August 2022 after obtaining FDA approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (*e.g.,* groin or axillae), in individuals 12 years of age or older. On October 6, 2023, we announced FDA approval of our sNDA to expand the indication of ZORYVE cream for the treatment of plaque psoriasis, including psoriasis in intertriginous areas, to children ages 6 to 11 years of age. Following this approval, ZORYVE cream is indicated for use in patients 6 years of age and older. In atopic dermatitis, we commercially launched ZORYVE cream 0.15% in July 2024 for the treatment of mild to moderate atopic dermatitis in adults and pediatric patients 6 years of age and older. We submitted a subsequent sNDA for ZORYVE cream 0.05% for 2-5 year olds in December 2024.

- ***Commercialize ZORYVE foam for the treatment of patients with seborrheic dermatitis and further expand our addressable market with the potential approval of the foam in scalp and body psoriasis.*** In December 2023, we received FDA approval for ZORYVE foam for the treatment of seborrheic dermatitis in individuals aged 9 years and older. ZORYVE foam became commercially available in late January 2024. We announced positive topline data from our Phase 3 scalp and body psoriasis trial in September 2022, and we submitted an sNDA to the FDA for a label expansion to include scalp and body psoriasis in adults and adolescents ages 12 and over, which was accepted by the FDA with a PDUFA target action date in May 2025.

- ***Exploit our integrated development and commercial organization to maximize the value of our products and product candidates.*** We have built a fully integrated commercial organization and a targeted specialty sales force for the commercialization of our products among dermatology specialists. Because of the concentrated prescriber base of the U.S. dermatology segment, we believe our infrastructure should be sufficient for us to commercialize our products to dermatology specialists. We have also partnered with Kowa to promote our approved ZORYVE in the United States to primary care practitioners and pediatricians. To further enhance the value of our product candidates, we have partnered with companies in Japan, China, and greater Asia to develop and commercialize ZORYVE, and may selectively seek additional partners to develop and commercialize our products in other markets.

- ***Execute our responsible pricing strategy and product access to enable rapid and high-quality insurance coverage and product access***. We are committed to helping patients have access to our product, including setting a responsible price, working with payers to help ensure broad high-quality payer access, and supporting programs like our Arcutis Cares™ patient assistance program and the ZORYVE Direct™ patient access support program.

- ***Further expand our product portfolio through the development of ARQ-255 and ARQ-252.*** We are developing ARQ-255 and ARQ-252, both of which contain ivarmacitinib, a JAK1 inhibitor with a high relative selectivity to JAK1 over Janus kinase type 2 (JAK2), for the treatment of alopecia areata, chronic hand eczema, and vitiligo. Given their high relative selectivity to JAK1 over JAK2, we believe ARQ-255 and ARQ-252 have the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition, which in turn gives them the potential to be best-in-class treatment options, if approved. We recently completed enrollment in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata and expect data in the first half of 2025. Reformulation efforts continue for ARQ-252.

- ***Develop ARQ-234 as a complimentary treatment to ZORYVE.*** We believe that ARQ-234, which we obtained through the acquisition of Ducentis in September 2022, has the potential to have a highly differentiated profile and could be a highly complimentary biologic treatment to ZORYVE for the treatment of atopic dermatitis, if approved. We believe our management team's experience in developing dermatological drugs, including biologics, will enable us to move ARQ-234 into the clinic and through the development process. ARQ-234 also has the potential to treat multiple other inflammatory diseases, which we may choose to pursue ourselves or through partnerships. Currently, we are working towards

submitting an IND during 2025.

- ***Leverage our product development platform to continue innovating and developing novel new treatments for dermatological diseases.*** Our expertise in dermatological clinical development and commercialization allows us to identify areas of high unmet needs, and our product development platform may allow us to develop novel new treatments that address those needs, as it has already with ZORYVE cream, ZORYVE foam, and ARQ-255.
- ***Evaluate strategic opportunities to in-license or acquire best-in-class dermatology assets consistent with our core strategy.*** Leveraging our deep expertise in identifying promising drug candidates, we will continue to seek best-in-class assets, similar to ARQ-234, 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 immunology and dermatology.

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

- Our innovative topical cream and foam formulations of ZORYVE (patented);
- The pharmacokinetic characteristics relating to improving delivery and extending half-life of both the cream and foam formulations of ZORYVE (patented);
- A novel topical cream without skin-drying surfactants (patent pending);
- A novel method for treating a fungal infection by administering a composition comprising roflumilast (patented);
- Our novel “4D” deep-penetrating formulation allowing topical delivery deeper in the dermis (patent pending); and
- A composition of roflumilast without a paraben preservative (patent pending).

ZORYVE Cream (ARQ-151)

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

We commercially launched ZORYVE cream 0.3% in August 2022 after obtaining FDA approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (e.g. groin or axillae), in individuals 12 years of age or older. ZORYVE cream 0.3% is approved for once-daily treatment of mild, moderate, and severe plaque psoriasis with no limitations on location or duration of use. In October 2023, we announced FDA approval of our sNDA to expand the indication of ZORYVE cream for the treatment of plaque psoriasis, including psoriasis in intertriginous areas (*e.g.*, groin or axillae), to children ages 6 to 11 years of age. Following this approval, ZORYVE cream is indicated for use in patients 6 years of age and older. We aim to further expand the indication in plaque psoriasis down to 2 years of age following the generation of additional clinical data.

We are also commercially launched topical ZORYVE cream 0.15% in July 2024 after obtaining approval for the treatment of mild to moderate atopic dermatitis in individuals 6 years and older. We have developed a lower-dose-concentration, ZORYVE cream 0.05%, and have completed our Phase 2 and Phase 3 studies in this population. Based on positive data, we submitted an sNDA in December 2024.

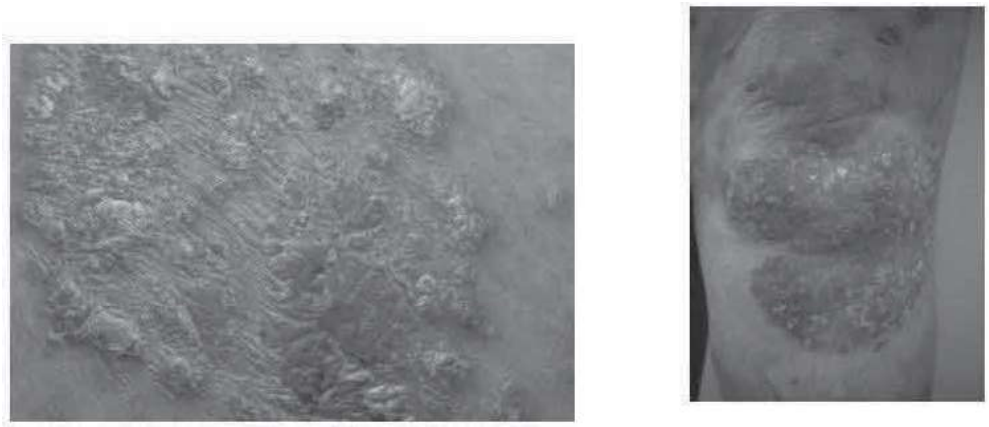
In July 2018, we executed a licensing agreement with AstraZeneca AB (AstraZeneca) for exclusive worldwide rights to roflumilast as a topical product in humans solely for dermatological indications. We have built our own intellectual property portfolio around topical uses of roflumilast, with issued and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

Plaque Psoriasis

Psoriasis Background

Psoriasis is an immune disease that occurs in about 3% of the U.S. population, representing approximately 9 million patients. About 90% of cases are plaque psoriasis, which is characterized by "plaques", or raised, red areas of skin covered with a silver or white layer of dead skin cells referred to as "scale" (see figures below). Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and the plaques are often itchy and sometimes painful. Approximately 40% of plaque psoriasis patients have plaques on their scalp, about 15% have plaques in their intertriginous regions, approximately 10% have plaques on their face, and one in three has plaques on their elbows and knees. Each of these areas present a variety of treatment challenges which may be well suited to treatment with ZORYVE cream.

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



Figures: Plaque Psoriasis

Source: DermNet (right)

Current Psoriasis Treatment Landscape

The vast majority of psoriasis patients are treated with topical therapies, of which there have been no novel treatments approved in over 20 years, until the recent approvals of ZORYVE cream and tapinarof. Despite their widespread use, other existing topical therapies all possess substantial shortcomings:

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



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

Source: DermNet (right)

- ***Vitamin D3 analogs*** provide substantially less symptomatic improvement than high potency steroids and are frequently irritating. While they can be used chronically, tolerability issues with their use can be a challenge, and physicians generally will not prescribe them for use on the face or in the intertriginous regions.
- ***Vitamin D3/steroid combinations*** offer better symptomatic improvement than either of the two individual components alone, but still carry a risk of HPA axis suppression, and are limited in their duration of use.
- **Tapinarof** is a non-steroidal topical aryl hydrocarbon receptor (AhR) agonist approved in May 2022 for adults with plaque psoriasis. In clinical trials, treatment with tapinarof was associated with folliculitis, contact dermatitis, burning, stinging, and itching.

Because high potency steroids and combinations containing high potency steroids provide robust symptomatic improvement for psoriasis patients, most physicians initiate treatment for nearly all patients with them. However, due to the limitations on duration of treatment to between 2 and 8 weeks, most physicians will switch the patient to a low- to mid-potency steroid or to a vitamin D analog to manage the patient's psoriasis chronically. These "step down" options provide less symptomatic improvement and are often irritating. Also, rebound is a known challenge with steroids, where the recurrence of psoriasis after steroid discontinuation is more severe than it was prior to steroid treatment. As a result, patients are constantly cycling between effective short courses of high potency steroids and less effective "step down" maintenance treatments.

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

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

Atopic Dermatitis

Atopic Dermatitis Background

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



Figures: Atopic Dermatitis

Source: DermNet

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

Current Atopic Dermatitis Treatment Landscape

The vast majority of atopic dermatitis patients are being treated with topical therapies, particularly low- to mid-potency topical steroids and TCIs, and these two classes of drugs constituted nearly all atopic dermatitis prescriptions in 2022. Despite their widespread use, existing topical therapies all possess substantial shortcomings:

- ***Topical steroids*** pose a particular concern in pediatric patients due to the risk of systemic absorption, and the consequent risk of HPA axis suppression, and potential developmental problems. Chronic use of topical steroids in atopic dermatitis patients is generally avoided. Many physicians are also reluctant to use steroids to treat atopic dermatitis on the face due to the increased risk of glaucoma and cataracts, or the diaper/groin region due to risk of skin thinning. There is also considerable concern among many parents about treating their children with steroids.
- ***Topical calcineurin inhibitors*** are generally seen as providing less symptomatic improvement than topical steroids and are also associated with some application site burning. In 2005 the FDA placed a boxed warning on the labels of both TCIs regarding a potential increased risk of cancers, especially lymphomas, associated with their use, which often creates significant parental resistance to their use.
- ***Eucrisa*** is a topical non-steroidal PDE4 inhibitor approved by the FDA in 2016. Despite initial interest among the physician community to adopt the product, its growth has been hampered by frequent occurrences of application site burning and stinging as well as disadvantaged reimbursement status compared to other atopic dermatitis treatments.
- ***Opzelura*** is a topical JAK inhibitor approved in September 2021 for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The label carries an extensive boxed warning for serious infections, all-cause mortality, malignancy, major adverse cardiovascular events and thrombosis.
- **Tapinarof** is a non-steroidal topical aryl hydrocarbon receptor (AhR) agonist approved in May 2022 for adults with plaque psoriasis. In clinical trials, treatment with tapinarof was associated with folliculitis, contact dermatitis, burning, stinging, and itching.

Treatment with biologics such as Dupixent®, as well as recently launched oral agents, remains highly restricted. In the United States, less than 5% of all atopic dermatitis patients are on biologic therapy. The uptake of biologics and systemic therapies is expected to grow, as the efficacy and dosing parameters of treatment options for moderate-to-severe disease states improve; however, similar to plaque psoriasis, we believe such use will ultimately remain limited due to multiple factors, including the fact that they are indicated only for use in moderate-to-severe patients, their high cost and patient co-payments, reimbursement and access restrictions, and patient fear of injection for biologics.

ZORYVE Cream Clinical Development

Plaque Psoriasis

We commercially launched ZORYVE cream in August 2022 after obtaining FDA approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (e.g. groin or axillae), in individuals 12 years of age or older. In October 2023, we received FDA approval for an expanded indication down to 6 years of age. We aim to further expand the indication in plaque psoriasis down to 2 years of age following the generation of additional clinical data. ZORYVE cream is approved for once-daily treatment of mild, moderate, and severe plaque psoriasis with no limitations on duration of use. Our NDA submission was supported by the positive data from the pivotal Phase 3 clinical studies, DERMIS-1 and DERMIS-2, and our long-term Phase 2b open label study. In all trials, ZORYVE cream was generally well-tolerated with a favorable safety and tolerability profile.

Key Completed Trials

DERMIS-1 and DERMIS-2 pivotal Phase 3 studies

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

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

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

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

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

In this open label study, ZORYVE cream 0.3% applied once daily for up to 52 weeks demonstrated favorable safety and tolerability over the long-term treatment period, consistent with what was seen in the randomized Phase 2b study, with only 3.6% of subjects experiencing a treatment-related adverse event during 52 weeks of treatment. Additionally, a durable treatment effect was maintained through 52 to 64 weeks as 57.1% (n=185) of ZORYVE cream-treated patients achieved an IGA score of clear or almost clear (IGA 0/1) at any time in study, and these participants had a median duration of IGA of clear or almost clear of more than 10 months (40.1 weeks). At week 52 of the long-term safety study, 44.8% of all subjects attained an IGA Success of clear or almost clear, with 34.8% of subjects in Cohort 1 and 39.5% of subjects in Cohort 2 achieving IGA Success, defined as a score of clear or almost clear plus a 2-grade improvement from baseline. Additionally, of the subjects in the 12-week randomized Phase 2b study who were treated with ZORYVE cream 0.3%, and who attained an IGA of clear or almost clear at 12 weeks in the first study, then continued on treatment in the long-term safety study, 66.7% had an IGA of clear or almost clear at the end of 64 weeks of treatment or their last visit. Of the 332 subjects in this study, 73.5% completed the full 52 weeks of open label treatment, with only 3.9% of subjects discontinuing the study due to an adverse event and less than 1% of subjects discontinuing due to lack of efficacy. There were no treatment related serious adverse events reported.

Atopic Dermatitis

We commercially launched ZORYVE cream 0.15% for the treatment of mild to moderate atopic dermatitis in adults and children down to age six in August 2024. Our NDA submission was based on three Phase 3 studies, as well as a Phase 2 dose-ranging study, and two Phase 1 pharmacokinetic studies. We have also developed ZORYVE cream 0.05% for the treatment of atopic dermatitis between the ages of 2 and 5 years of age. Based on positive data of our two Phase 3 studies in this age group, we submitted an sNDA in December 2024.

Key Completed Trials

INTEGUMENT-1 and INTEGUMENT-2 pivotal Phase 3 studies

Our atopic dermatitis Phase 3 program includes three 4-week pivotal studies and a 52-week open label extension study. The INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis (INTEGUMENT) 1 and 2 were multi-center, double-blind, vehicle-controlled Phase 3 studies, with more than 650 subjects in each study, ages 6 and above with mild to moderate atopic dermatitis. Subjects were randomized to receive once daily topical applications for 4 weeks of ZORYVE cream 0.15%, or vehicle. The primary endpoint was the proportion of all randomized subjects who attain IGA Success, defined as a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of 'clear' or 'almost clear' plus a 2-grade improvement from Baseline at Week 4.

Both INTEGUMENT-1 and INTEGUMENT-2 met their primary endpoint. In INTEGUMENT-1, 32.0% of individuals treated with ZORYVE cream 0.15% achieved IGA Success, compared to 15.2% of individuals treated with vehicle (P<0.0001). In INTEGUMENT-2, 28.9% of individuals treated with ZORYVE cream 0.15% achieved IGA Success at Week 4 compared to 12.0% of individuals treated with vehicle (P<0.0001). ZORYVE cream also demonstrated rapid and statistically significant improvements compared to vehicle on key secondary endpoints, including, in INTEGUMENT-1, 43.2% of individuals treated with ZORYVE cream 0.15% achieving a 75% improvement in Eczema Area and Severity Index (EASI-75) at Week 4 compared to 22.0% treated with vehicle (P<0.0001). In INTEGUMENT-2, 42.0% of individuals treated with ZORYVE cream 0.15% achieved an EASI-75 at Week 4 compared to 19.7% treated with vehicle (P<0.0001).

In an additional secondary endpoint, INTEGUMENT-1 evaluated reduction in itch in individuals 12 years of age and older, with 33.6% of individuals treated with ZORYVE cream achieving a 4-point reduction in Worst Itch Numeric Scale (WI-NRS) at Week 4 (vs. 20.7% for vehicle-treated subjects [p<0.01]). For INTEGUMENT-2, 30.2% of individuals treated with ZORYVE cream achieving a four-point reduction in WI-NRS at Week 4 (vs. 12.4% for vehicle-treated subjects, [P<0.01]). In addition, individuals treated with ZORYVE cream reported reductions in itch from baseline as early as 48 hours from first application. ZORYVE cream 0.15% was well tolerated in both studies. The incidence of Treatment Emergent Adverse Events (TEAEs) was low in both active treatment and vehicle arms, with most TEAEs assessed as mild-to-moderate severity. Overall, incidence of adverse events were low, with no adverse event occurring in more than 3.5% of subjects in either arm for either INTEGUMENT-1 or INTEGUMENT-2. The most frequent adverse events (≥1%) included COVID-19, application site pain, headache, nausea, vomiting, diarrhea, nasopharyngitis, and upper respiratory tract infection. Over 90% of patients who were randomized to ZORYVE cream in both studies completed the full 4 weeks, and there were few discontinuations due to adverse events.

INTEGUMENT-PED Trial

In September 2023, we announced positive topline data from INTEGUMENT-PED trial. This pivotal trial investigated ZORYVE cream 0.05% as a potential treatment for children 2 to 5 years of age with mild to moderate atopic dermatitis. The trial was a Phase 3, randomized, parallel group, double-blind, vehicle-controlled trial in which subjects ages 2 to 5 with mild to moderate atopic dermatitis involving 3% or greater body surface area received 4 weeks of (i) ZORYVE cream 0.05% once daily or (ii) vehicle once daily. A total of 652 children were enrolled in INTEGUMENT-PED.

Results from the four-week treatment period demonstrated statistically significant improvements compared to matching vehicle. The primary endpoint was the percentage of patients achieving IGA success, which is vIGA-AD score of "clear" or "almost clear" plus a 2-grade improvement from baseline, at Week 4. In the trial, 25.4% of patients treated with ZORYVE cream 0.05% achieved IGA success, compared to 10.7% of patients treated with vehicle ($p < 0.0001$), with significant improvements observed as early as Week 1.

ZORYVE cream 0.05% also demonstrated statistically significant improvements compared to vehicle on key secondary endpoints, which included EASI-75, the percentage of patients achieving IGA success at Weeks 1 and 2, and the percentage of patients achieving a vIGA-AD score of “clear” or “almost clear” at Weeks 1 and 2, with significant improvements observed for these endpoints as early as Week 1. In the trial, 39.4% of patients treated with ZORYVE cream 0.05% achieved EASI 75 at Week 4, compared to 20.6% of patients treated with vehicle ($p < 0.0001$). In addition, 21.2% of patients achieved IGA success at Week 2, compared to 6.8% of patients treated with vehicle ($p < 0.0001$), and 9.4% of patients achieved IGA success at Week 1, compared to 0.9% of patients treated with vehicle ($p < 0.0001$). In the trial, 35.3% of patients treated with ZORYVE cream 0.05% with an itch score of at least four at baseline achieved a four-point reduction in itch score compared to baseline, as measured by the WI-NRS, compared to 18.0% of patients treated with vehicle ($p = 0.0002$).

ZORYVE cream 0.05% was well-tolerated, with rates of treatment-emergent adverse events (TEAEs) low across the active treatment and vehicle arms. Overall, adverse events were uncommon, with no adverse event occurring in more than 4.1% of subjects in the trial. The only adverse event occurring in >3% of subjects in either arm was upper respiratory tract infection, and the most frequent adverse events (>2%) included upper respiratory tract infection, pyrexia, diarrhea, vomiting, and, in the vehicle arm only, atopic dermatitis.

Of the patients treated with ZORYVE cream 0.05% in the trial, 410 (93.8% of patients) completed the full 4 weeks, and there were few discontinuations due to adverse events in both the ZORYVE cream 0.05% group and vehicle group. Five patients treated with ZORYVE cream 0.05% (1.1% of patients treated with ZORYVE cream 0.05%) and four patients in the vehicle group (1.9% of patients treated with vehicle) discontinued the trial due to an adverse event. There were no treatment-related serious adverse events.

INTEGUMENT OLE (long range study)

In addition, our “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis Open Label Extension” (INTEGUMENT-OLE) study is a Phase 3, multicenter, open label extension study that has enrolled 1220 subjects who have completed INTEGUMENT-1, -2, or -PED. The study examines the long-term safety of ZORYVE cream 0.15% in subjects 6 years of age and older with atopic dermatitis and ZORYVE cream 0.05% in subjects 2 to 5 years of age with atopic dermatitis. The primary objective of the study is to assess the long-term safety based on the occurrence of adverse events and serious adverse events. Individuals that completed INTEGUMENT-1 and -2 are eligible to enroll for either 24 or 52 weeks of additional treatment, representing 28 or 56 weeks of treatment in aggregate.

In September 2023, we announced positive interim results from this ongoing study regarding subjects 6 years of age and older with atopic dermatitis. A total of 657 subjects had been enrolled in INTEGUMENT-OLE at such time. After 4 weeks of treatment, subjects who achieved a vIGA-AD score of “clear” transitioned to twice weekly maintenance dosing, after which any subjects who reached a vIGA-AD score of “mild” would resume once-daily dosing. Subjects could also resume once-daily dosing if signs or symptoms were not adequately controlled with maintenance dosing despite maintaining a vIGA-AD score of “almost clear.” More than two-thirds of participants who transitioned to maintenance dosing remained on the twice weekly maintenance dosing schedule for more than half of their time in the trial.

Results from the study demonstrated long-term safety and a tolerability profile consistent with data from our INTEGUMENT-1 and -2 trials, with no new safety signals observed up to 56 weeks of treatment. Rates of TEAEs were generally consistent with INTEGUMENT-1 and -2, with 241 subjects (36.7% of subjects) experiencing any TEAE and 31 subjects (4.7% of subjects) experiencing treatment-related TEAEs. No adverse event occurred in more than 4.6% of subjects. The only adverse events occurring in >2% of subjects included COVID-19, upper respiratory tract infection, nasopharyngitis and headache, and 21 subjects (3.2% of subjects) discontinued the study due to adverse events. There were eight subjects (1.2% of subjects) with serious adverse events and no treatment-related serious adverse events.

ZORYVE cream 0.15% also performed well on secondary endpoints, including IGA success, which was defined as a vIGA-AD score of "clear" or "almost clear" plus a 2-grade improvement from baseline in INTEGUMENT-1 or -2, and EASI-75. For example, 46.1% and 51.0% of patients treated with ZORYVE cream 0.15% achieved IGA success in Week 28 and 56, respectively, compared to 41.5% and 44.6%, respectively, of patients treated with vehicle. In addition, 61.5% and 66.2% of patients treated with ZORYVE cream 0.15% achieved EASI-75 at Week 28 and 56, respectively, compared to 60.9% and 64.6%, respectively, of patients treated with vehicle.

In August 2024, we announced positive results for subjects 2 to 5 years old. In the study, ZORYVE cream 0.05% was well-tolerated, with no new safety signals observed during treatment of up to 56 weeks in duration. Efficacy results were not only maintained but also improved over time, with 71.9% of participants who rolled over from the roflumilast cream 0.05% treatment arm in INTEGUMENT-PED achieving EASI 75 after 56 weeks. Overall incidence of adverse events was low, with most being mild to moderate in nature. The most frequently reported adverse events (≥3%) included: upper respiratory tract infection, nasopharyngitis, pyrexia, influenza, COVID-19, and otitis media.

We believe these results demonstrate the durability of treatment and the potential for improvement in patient symptoms over time.

ZORYVE Foam (ARQ-154)

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

In December 2023, we received FDA approval for ZORYVE foam for the treatment of seborrheic dermatitis in individuals aged 9 years and older, with no limitation on severity, location, or duration of use. ZORYVE foam has been shown to provide rapid disease clearance and significant reduction in itch in clinical studies. In a pivotal Phase 3 study, 80% of individuals treated with ZORYVE foam achieved the primary efficacy endpoint of IGA Success, defined as an IGA score of “clear” or “almost clear” plus a 2-point improvement at Week 8. and just over 50% of individuals achieved an IGA score of clear at Week 8. In addition, individuals treated with ZORYVE foam reported reductions in itch from baseline within 48 hours of first application. ZORYVE foam is a once-daily steroid-free foam and the first drug approved for the treatment of seborrheic dermatitis with a new mechanism of action in over two decades. ZORYVE foam became commercially available in late January 2024.

We have successfully completed our pivotal Phase 3 study of ZORYVE foam in scalp and body psoriasis (ARRECTOR), demonstrating promising efficacy and tolerability results. We announced positive topline data in September 2022, and have submitted our sNDA with a PDUFA in May 2025. We believe that ZORYVE foam could offer physicians and patients a highly differentiated clinical profile that is ideally suited to address unmet needs in the topical treatment of seborrheic dermatitis and potentially scalp and body psoriasis.

Seborrheic Dermatitis

Seborrheic Dermatitis Background

Seborrheic dermatitis is a common skin disease that is estimated to occur in more than 10 million people in the United States. The disease causes red patches covered with large, greasy, flaking yellow-gray scales, and is frequently itchy. It appears most often on the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back as depicted in the figures below. While the pathogenesis of seborrheic dermatitis is not well understood, it is an inflammatory disease of the skin distinct from atopic dermatitis and psoriasis, it shares some features such as a skin barrier defect with atopic dermatitis and some inflammatory pathways in common with psoriasis. Seborrheic dermatitis is associated with an over-abundance of *Malassezia*, a naturally occurring yeast found on normal skin but found in excess numbers on skin with seborrheic dermatitis where it may exacerbate the underlying skin inflammation that leads to the signs and symptoms well characterized in the disease. Seborrheic dermatitis can occur in adults, adolescents and infants, and in infants is commonly referred to as “cradle cap”.



Figures: Seborrheic Dermatitis

Current Seborrheic Dermatitis Treatment Landscape

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

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

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

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

Scalp Psoriasis

Scalp Psoriasis Background

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



Figures: Scalp Psoriasis

Source: DermNet (left)

Current Scalp Psoriasis Treatment Landscape

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

Seborrheic Dermatitis

Key Completed Trials

STRATUM pivotal Phase 3 Study

The "STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis" (STRATUM) was a Phase 3, parallel group, double blind, vehicle-controlled study of the safety and efficacy of ZORYVE foam 0.3% administered once-daily. A total of 457 subjects ages 9 and older with moderate to severe seborrheic dermatitis were enrolled in the study and randomized 2:1 to ZORYVE foam or vehicle. A significant percentage of patients had seborrheic dermatitis in more than one location on their body and more than half of patients had facial seborrheic dermatitis, including a subset with seborrheic dermatitis on their eyelids. The primary endpoint of the study was the proportion of subjects achieving IGA Success, defined as an IGA score of “clear” or “almost clear” plus a 2-point improvement at Week 8.

The study met the primary endpoint, with 79.5% of individuals treated with ZORYVE foam achieving IGA Success at Week 8, compared to 58.0% of patients treated with vehicle (P<0.0001). Improvement with ZORYVE foam was seen early, with ZORYVE separating statistically from vehicle on IGA Success at Week 2. In addition, 50.6% of patients treated with ZORYVE foam achieved an IGA score of clear at Week 8, compared to 28.2% of patients treated with vehicle ($p < 0.0001$). ZORYVE foam also demonstrated statistically significant improvements compared to vehicle on key secondary endpoints, including itch as measured by Worst Itch-Numerical Rating Score (WI-NRS). 62.8% of patients with a Worst Itch-Numerical Rating Score of 4 or higher at baseline treated with ZORYVE foam achieved a 4-point or greater reduction in itch at Week 8, compared to patients treated with vehicle ($p = 0.0001$). Individuals treated with ZORYVE foam reported a 28% improvement in itch from baseline as early as 48 hours after the first application, compared to 13% of patients treated with vehicle (p=0.0024).

ZORYVE foam was well-tolerated. The incidence of TEAEs was low and similar between active treatment and vehicle, with most TEAEs assessed as mild-to-moderate severity. There were no treatment-related serious adverse events. Overall, the most common adverse events in the study population (over 1%) included nasopharyngitis, nausea and headache.

ARQ-154-214 (Long-Term Safety)

Study ARQ-154-214 was a multi-center, open label Phase 2 long-term safety study of ZORYVE foam 0.3% applied once daily in subjects with seborrheic dermatitis. This study included subjects who were treated previously in the Phase 2 trial (ARQ-154-203), as well as subjects naive to treatment with ZORYVE foam. Periodic clinic visits assessed clinical safety, application site reactions, and disease improvement, or progression. The study demonstrated sustained durability of results for up to 52 additional weeks of treatment, as well as a favorable safety and tolerability profile consistent with earlier Phase 2 and Phase 3 studies in seborrheic dermatitis.

Scalp Psoriasis

Key Completed Trials

ARRECTOR pivotal Phase 3 Study

The "A Randomized tRial Employing topiCal roflumilasT foam to treat scalp psORiasis" (ARRECTOR) study was a parallel group, double blind, vehicle-controlled pivotal Phase 3 study of the safety and efficacy of ZORYVE foam 0.3% or a matching vehicle administered once-daily in subjects with scalp and body psoriasis ages 12 and older. A total of 432 subjects were enrolled in the study and randomized 2:1 to ZORYVE foam or vehicle. The co-primary endpoints of the study were the proportion of subjects achieving scalp IGA (S-IGA) success and the proportion of subjects achieving body IGA (B-IGA) success, with IGA success on both endpoints defined as an IGA score of 'clear' or 'almost clear' plus a 2-point improvement from baseline after 8 weeks.

The study met both co-primary endpoints and all secondary endpoints. Specifically, 67.3% of individuals treated with ZORYVE foam achieved S-IGA Success at Week 8, compared to 28.1% of individuals treated with vehicle (P<0.0001), and 46.5% of individuals treated with ZORYVE foam achieved B-IGA Success at Week 8, compared to 20.8% of individuals treated with vehicle (P<0.0001). ZORYVE foam also demonstrated statistically significant improvements compared to vehicle on all secondary endpoints, including scalp itch as measured by Scalp Itch Numeric Rating Scale (SI-NRS) and overall itch as measured by Worst Itch-Numerical Rating Score (WI-NRS).

ZORYVE foam was well-tolerated, with the incidence of TEAEs low and generally similar to vehicle, with most TEAEs assessed as mild-to-moderate severity. Overall, the most common adverse events in the study population (over 2%) included headache, diarrhea, and COVID-19. In the study, 89.0% of patients who were treated with ZORYVE foam completed the full 8 weeks, and few subjects discontinued the study due to adverse events (2.5% of subjects treated with ZORYVE foam and 1.3% of the subjects in the vehicle group).

ARQ-234

In September 2022, we acquired Ducentis and its lead asset, DS-234 (now ARQ-234), a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 Receptor (CD200R). CD200R is an immune-regulatory receptor that is thought to be an important immunological checkpoint with a pivotal role in the maintenance of immune tolerance. Checkpoint agonism is an emerging immunomodulatory approach that works to amplify pathways that inhibit over-active immune cells and suppress unwanted immune responses. ARQ-234 binds to CD200R and has the potential to restore immune homeostasis by inducing inhibitory signaling on immune cells that regulate inflammation.

CD200R has been validated as a target in atopic dermatitis, with preclinical data for ARQ-234 and clinical data for a similar molecule under development by another company each providing evidence of a robust and durable therapeutic response, even after discontinuation of treatment. Ducentis completed preclinical comparisons of ARQ-234 against the clinically-validated CD200R antibody. The data compare favorably across key metrics including potency, efficacy, and pharmacokinetics and indicated potential differentiation from the clinically-validated CD200R antibody with an improved ability to modulate the CD200R pathway, a longer half-life, and a higher steady state volume of distribution. We plan to develop ARQ-234 in atopic dermatitis, where it could be a potentially highly complementary treatment option to ZORYVE cream in that indication, if approved. We believe the acquisition of this preclinical asset is a transformative opportunity for Arcutis and, in leveraging our team's deep dermatology expertise and broad biologics experience, that our leadership and operational team will enable us to move ARQ-234 into the clinic and through the development process. We are working towards submitting an IND in 2025.

ARQ-255

We are developing ARQ-255, an innovative topical formulation of ivarmacitinib, a potent and highly selective small molecule inhibitor of JAK1, for the treatment of alopecia areata. Alopecia areata is an autoimmune disorder that causes the immune system to incorrectly attack the body's own cells, specifically the hair follicles, leading to loss of hair—usually in patches—on the scalp, face, or sometimes other areas of the body. While oral JAK inhibitors have shown symptomatic improvement in the treatment of alopecia areata and baricitinib is FDA approved for this indication, multiple topically applied JAK inhibitors have failed to demonstrate symptomatic improvement in alopecia areata. It is our belief that this discrepancy is due to the site of inflammation driving alopecia areata, deep in the skin at the base (bulb) of the hair follicle. While oral JAK inhibitor administration can achieve required levels of drug at the site of inflammation, conventional topical applications are unlikely to deliver concentrations of JAK inhibitors to the site of inflammation adequate to treat alopecia areata. We have developed a unique drug delivery technology that we refer to as Deep Dermal Drug Delivery ("4D" technology), which we believe may allow us to topically deliver sufficient concentrations of ivarmactinib deep down the hair follicle to the site of inflammation, to potentially treat alopecia areata via topical administration. Additionally, in a nonclinical study, ivarmactinib proved to be highly selective to JAK1 over JAK2. We believe that due to its high selectivity for JAK1 over JAK2, ARQ-255 has the potential to treat inflammatory diseases without causing the hematopoietic adverse effects associated with JAK2 inhibition.

Alopecia Areata

Alopecia Areata Background

Alopecia areata is an autoimmune condition that affects about 1 in 500 adults. In alopecia areata, the immune system attacks the body's own hair follicles—leading to patches of hair loss on the scalp, face, and other areas of the body. Typically, these bald patches appear suddenly and in some patients, can involve the whole body. Recurrence is common and most sufferers will have several episodes during their lifetimes. A small percentage of patients have persistent hair loss even with treatment. Alopecia areata has been shown to lead to significant psychosocial impacts in patients, negatively impacting self-esteem, body image, and/or self-confidence.

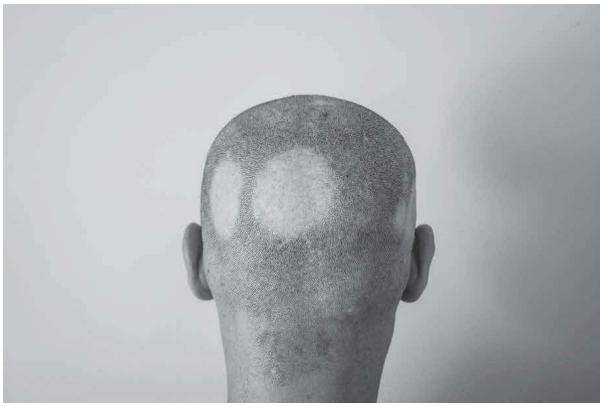


Figure: Alopecia Areata

Current Alopecia Areata Treatment Landscape

In addition to the oral JAK inhibitor baricitinib, which was approved in June 2022, most patients are treated with off-label steroids for alopecia areata.

- **JAK inhibitor (baricitinib),** approved only for severe alopecia areata and the only JAK inhibitor approved for alopecia areata, however, it carries an extensive black box warning on its label in the United States. Topical JAK inhibitors to date have not demonstrated efficacy in alopecia areata and, other than ARQ-255, we believe that there are no other topical development programs progressing currently.
- **Topical and intralesional steroids**, typically topical super potent steroids or intralesional injections of triamcinolone, are often prescribed for patients suffering from alopecia areata because of the inflammatory component of the disease. Due to the risks associated with steroid use, including atrophy and systemic exposure from intralesional injections, many physicians try to limit duration or avoid steroid therapy.

A growing body of evidence indicates that inhibition of JAK signaling in alopecia areata can effectively promote hair regrowth. We believe ARQ-255 may present a unique opportunity to treat alopecia areata topically. The current approved treatment option is for oral treatment of severe disease, and we believe that a substantial unmet medical need remains for patients with mild and moderate disease states. In addition, the safety profile of oral baricitinib presents an opportunity for treatment in severe patients who may need to limit the chronic exposure to systemic JAK inhibition and potential risks of cancer, infection, and other identified risks.

ARQ-255 Clinical Development

Alopecia Areata

ARQ-255-126 Study (Phase 1b Study)

We completed enrollment in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata and expect data in the first half of 2025. The Phase 1b study is a vehicle-controlled, double-blind, multi-center study designed to evaluate the safety, tolerability, and pharmacokinetics of treatment with ARQ-255 topical suspension 3% or vehicle in healthy adult subjects and individuals with patchy alopecia areata.

ARQ-252

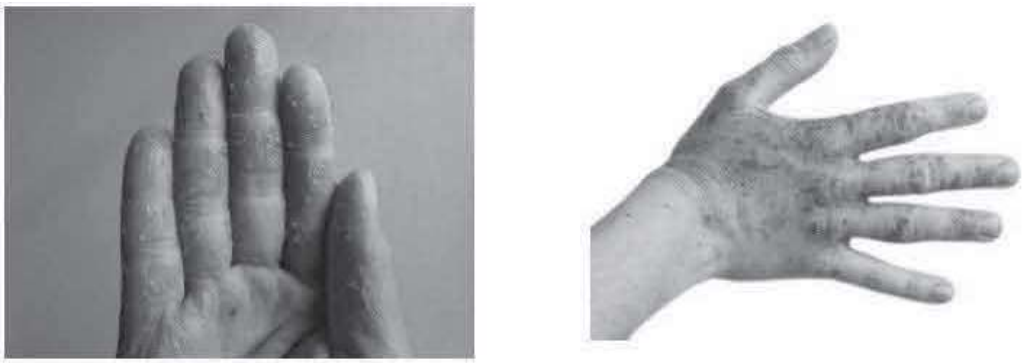
ARQ-252 is an alternative topical cream formulation of ivarmacitinib that we are developing for chronic hand eczema and vitiligo. As the only JAK1-selective topical in development, we believe that ARQ-252 could offer a best-in-class topical JAK inhibitor, with a more favorable safety and tolerability profile than other topical JAK inhibitors due to its selectivity to JAK1 over JAK2, robust symptomatic improvement due to its high potency against JAK1, and a convenient and patient-friendly cream formulation.

In May 2021, we announced that the Phase 1/2b study of ARQ-252 in chronic hand eczema did not meet its primary endpoint, with further analyses of the study pointing to inadequate local drug delivery to the skin. Importantly, there were no safety or tolerability issues seen in that study. Given these analyses, we also elected to terminate the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment in vitiligo, as we began reformulation efforts to develop an enhanced formulation of ARQ-252 that delivers more active drug to targets in the skin. The ARQ-255 formulation, a topical suspension using our 4D technology, is separate and distinct from the ARQ-252 cream formulation, and thus there are no implications to ARQ-255 from ARQ-252.

Chronic Hand Eczema

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

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



Figures: Hand Eczema

Current Hand Eczema Treatment Landscape

Hand eczema is a difficult disease to treat. The palms of the hand have skin that can be up to ten times thicker than skin from other body areas, which inhibits drug absorption and the ability to deliver drugs topically. Hand eczema is typically treated with high potency topical steroids, mostly due to the aforementioned skin barrier challenges. In some cases, physicians also will incorporate barrier creams to aid in hydration and to prevent the irritant effect caused by occupational exposure, a common cause of hand eczema. There are currently no FDA-approved treatments specifically for the indication of hand eczema. However, LEO Pharma has reported positive Phase 3 study results for their topical JAK inhibitor, delgocitinib. Physicians report that a significant percentage of patients, including up to 40% of patients with severe dyshidrotic eczema (one type of hand eczema), have an inadequate response to currently available treatments. In those who respond to high potency topical steroids, skin atrophy becomes a problem with chronic use, even on the thick skin of the palms.

Vitiligo

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

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

Competition

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

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

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

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

For psoriasis, our primary competitors include injected biologic therapies such as Humira®, marketed by AbbVie Inc. and Eisai Co., Ltd., and Enbrel®, marketed by Amgen Inc.; Pfizer Inc., and Takeda Pharmaceutical Company Limited; non-injectable systemic therapies used to treat plaque psoriasis such as Otezla, marketed by Amgen Inc., and Sotyktu®, marketed by Bristol Myers Squibb; topical therapies such as tapinarof, marketed by Organon; 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.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc.; Opzelura, marketed by Incyte Corporation; which was approved in September 2021, and generic and branded versions of low to mid-potency steroids such as hydrocortisone or triamcinolone. In the moderate-to-severe setting, the injected biologic therapy Dupixent, marketed by Regeneron Pharmaceuticals, Inc; is approved, as well as the recently approved injectable biologic therapy Adbry®, marketed by LEO Pharma. Non-injectable systemic therapies RINVOQ® and CIBINQO® were also recently approved in moderate-to-severe atopic dermatitis. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with ZORYVE cream and ARQ-234, including but not limited to: topical tapinarof, under development by Organon, topical delgocitinib, under development by LEO Pharma A/S and Japan Tobacco, Inc. (approved as Corectim in Japan), topical PF-07038124, under development by Pfizer Inc, topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, injectable lebrikizumab, under development by Eli Lilly and Company, injectable rocatinlimab, under development by Amgen, and injectable amlitelimab, under development by Sanofi.

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, especially Olumiant® (baricitinib), marketed by Eli Lilly and Company, an oral JAK inhibitor and the first FDA-approved treatment for alopecia areata. 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: ritlecitinib, under development by Pfizer, Inc., and deuruxolitinib (CTP-543), under development by Concert Pharmaceuticals (being acquired by Sun Pharmaceuticals).

For hand eczema, our primary competitors include topical therapies such as branded and generic versions of clobetasol, such as Clobex, and generic versions of betamethasone dipropionate. The only other prescription product candidate we are aware of under development for the treatment of hand eczema that would compete with ARQ-252 is delgocitinib, under development by LEO Pharma A/S, which has reported positive Phase 3 results.

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; the topical JAK inhibitor Opzelura, marketed by Incyte Corporation; 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-255, including but not limited to: oral PF-06651600 and oral PF-06700841, both under development by Pfizer Inc.

Commercial Operations

We intend to commercialize ZORYVE and our other product candidates ourselves in the United States and Canada within the dermatology specialty. In the United States, we have completed the build-out of our commercial organization, including marketing, market access, sales and marketing operations, and professional relations. We have also built our own focused specialty sales force to target dermatologists in the United States. We may seek partnerships that allow us to target other physicians, especially pediatricians, allergists, and primary care physicians in the United States, to maximize the potential of our product candidates. In Canada, we built the limited infrastructure that we believe is required to support the commercialization of our products in Canada. We may also seek other partners to help us access other geographic markets.

Intellectual Property

Maintaining proprietary rights in our product candidates and technologies will assist in achieving the success of our business. One way in which we obtain and maintain such proprietary rights is by filing patent applications and maintaining patents covering our core technologies and product candidates. Our policy is to file such patent applications in the United States and select foreign countries to better protect our worldwide interests. We also seek to avoid infringing the proprietary rights of others. For this reason, we routinely monitor and evaluate third-party patents and publications, and, if necessary, take appropriate action based on that evaluation. Patent term is based on the filing or grant date of the patent, as well as the governing law of the country in which the patent is obtained. In the United States, some pharmaceutical patents are also eligible for Patent Term Extension, or PTE, which can extend exclusivity for up to five additional years under certain conditions. The protection provided by a patent varies from country to country, and is dependent on the type of patent granted, the scope of the patent claims, and the legal remedies available in a given country.

As of February 25, 2025, we own or have an exclusive license to 32 issued U.S. patents and 58 issued foreign patents, which include granted European patent rights that have been validated in various European Patent Organization (EPO) member states, and 31 pending U.S. patent applications, 200 pending foreign patent applications, including 4 applications filed under the Patent Cooperation Treaty. Of these patents and patent applications:

- **Roflumilast cream & roflumilast foam**: As of February 25, 2025, we own 20 issued U.S. patents, three issued Australian patents, three issued Canadian patents, two issued Chinese patents, two issued Eurasian patents, two issued European patents (validated in various EPO member states), one issued Hong Kong patent, two issued Indian patents, two issued Israeli patents, seven issued Japanese patents, three issued Mexican patents, two issued New Zealand patents, and two issued South Korean patents. We also own 19 pending U.S. patent applications, and 76 pending foreign applications (four in Australia, seven in Brazil, five in Canada, ten in China, one in Eurasia, eight in Europe, seven in Hong Kong, two in India, five in Israel, five in Japan, four in Mexico, seven in New Zealand, five in South Korea, three in Singapore, and three under the Patent Cooperation Treaty), relating to a roflumilast cream and/or roflumilast foam. Twelve of our U.S. patents are listed in the FDA's Orange Book for our roflumilast 0.15% and 0.3% cream products, and thirteen of our U.S. patents are listed in the Orange Book patents for our roflumilast 0.3% foam product. The issued U.S. patent that we have licensed from AstraZeneca claiming a composition of matter encompassing roflumilast, the active pharmaceutical ingredient in roflumilast cream and roflumilast foam, expired on January 27, 2020. Data exclusivity for oral roflumilast expired on January 23, 2021. Our issued patents relating to a roflumilast cream and/or a roflumilast foam contain claims directed to, among other things, pharmaceutical compositions comprising roflumilast and hexylene glycol, pharmaceutical compositions comprising roflumilast and diethylene glycol monoethyl ether, pharmaceutical compositions comprising roflumilast and cetostearyl alcohol, dicetyl phosphate, and ceteth-10 phosphate, methods of making such compositions, and methods of treatment using such compositions, methods of treating fungal infections by administering compositions comprising roflumilast, and methods for improving treatment adherence by improving delivery and extending the plasma half-life of a roflumilast composition. These issued U.S. patents relating to roflumilast cream and roflumilast foam will expire not earlier than June 2037. We also have a method of treatment patent for roflumilast foam in the treatment of seborrheic dermatitis which expires 2041. Our pending patents relating to roflumilast cream and roflumilast foam contain claims directed to,

among other things, pharmaceutical compositions comprising roflumilast and diethylene glycol monoethyl ether, pharmaceutical compositions comprising roflumilast, cetostearyl alcohol, dicetyl phosphate, and/or ceteth-10 phosphate, methods of treatment using such compositions, methods of manufacturing such compositions, and other aspects of our roflumilast formulations, including unique pharmacokinetic aspects of topical roflumilast compositions.

- **ARQ-252 & ARQ-255**: As of February 25, 2025, we have an exclusive license from Hengrui to six issued U.S. patents, five issued Japanese patents, and five issued EU patents (validated in various EPO member states) relating to ivarmacitinib. These patents and patent applications contain claims directed towards the composition of matter of the ivarmacitinib compound and bisulfate and crystalline forms thereof, pharmaceutical compositions and treatment methods. The issued patents and pending applications, if issued, relating to ivarmacitinib will not begin to expire until December 2032. We own four issued U.S. patents, two issued Japanese patents, and have filed four pending U.S. patent applications and 44 pending foreign patent applications (three in each of Australia, Brazil, Canada, China, Europe, India, Israel, Japan, Mexico, Singapore, South Korea, and New Zealand, two in each of Hong Kong, Indonesia, Thailand, and Vietnam) relating to, among other things, ivarmacitinib compositions and methods of treatment using ivarmacitinib compositions. We anticipate filing additional patent applications directed towards compositions, methods and other aspects of our technology relating to ARQ-252 and ARQ-255 which we may develop in the future.
- **ARQ-234 and other CD200 mutant proteins**: As of February 25, 2025, we own one issued U.S. patent, one issued Australian patent, one issued Chinese patent, one issued Eurasian patent, one issued Israeli patent, one issued Indian patent, one issued Japanese patent, one issued Mexican patent, two issued South Korean patents, one issued Singapore patent, one issued South African patent, and 3 pending U.S. applications, and 37 pending foreign applications (four in each of Canada and Europe, three in each of China, Japan, and New Zealand, two in each of Australia, Brazil, India, Israel, and South Korea, and one in each of Eurasia, Great Britain, Hong Kong, Indonesia, Mexico, Philippines, Singapore, South Africa, Thailand, and the Patent Cooperation Treaty), relating to ARQ-234 and other CD200 mutant proteins.

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

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

License, Collaboration and Co-Promotion Agreements

Kowa Co-Promotion Agreement

In July 2024, we entered into a co-promotion agreement with Kowa Pharmaceuticals, Inc. to leverage Kowa's primary care sales force to exclusively market and promote ZORYVE in the United States to primary care practitioners and pediatricians for all FDA-approved indications until at least July 2029. Under the terms of the agreement, Kowa receives a commission from net sales attributed to Kowa. Promotion of ZORYVE in primary care and pediatrics under the Kowa agreement began in late September2024.

Sato License Agreement

On February 27, 2024, we entered into a License Agreement with Sato Pharmaceutical Co., Ltd. (Sato). Pursuant to the terms of the License Agreement, we grant to Sato an exclusive, sublicensable (under certain circumstances) license under certain patent rights and know-how controlled by us for Sato to develop, conduct medical affairs activities for, manufacture, commercialize, and otherwise exploit roflumilast formulations (the

Licensed Products) for all therapeutic uses for certain dermatological indications in humans (the Field) in Japan (the Territory).

The License Agreement sets forth each party's respective obligations with respect to the development, medical affairs activities, manufacture and supply, and commercialization of the Licensed Products. Pursuant to the terms of the License Agreement, Sato will, at its expense, develop, obtain regulatory approval for, commercialize, and conduct medical affairs activities related to the Licensed Products in the Field in Japan, subject to certain of our approval and oversight rights.

Pursuant to the terms of the License Agreement, we received an upfront payment of $25.0 million and will potentially receive additional payments (i) up to an aggregate amount of $10.0 million upon the achievement of certain regulatory milestones and (ii) up to an aggregate amount of $30.0 million upon the achievement of certain sales milestones. In addition, on a Licensed Product-by-Licensed Product basis, commencing from the first commercial sale of such Licensed Product in Japan until the latest of (i) the expiration of the last valid claim in the intellectual property rights licensed by us to Sato under the License Agreement covering such Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Licensed Product in Japan, or (iii) ten years after the first commercial sale of such Licensed Product in Japan, we will receive low double-digit to mid-teen double-digit percentage royalties on Sato's, its affiliates' and sublicensees' total annual net sales of all Licensed Products, subject to certain royalty reductions.

The term of the License Agreement continues until, on a Licensed Product-by-Licensed Product basis, the expiration of the Royalty Term. The License Agreement may be terminated by either party in its entirety if the other party commits a material breach, subject to a cure period, or if the other party becomes insolvent. Sato may terminate the License Agreement at-will in its entirety upon 90 days' written notice. Unless unenforceable under applicable law, we may terminate the License Agreement in its entirety if Sato, its affiliate or sublicensee contests or assists a third party in contesting the scope, validity or enforceability of any patent or patent application licensed by us to Sato. We may also terminate the License Agreement if Sato or any director, officers, employee, agent, affiliate, sublicensee, or subcontractor is charged by a governmental authority for a violation of any anti-corruption, anti-money laundering, sanctions or export or import control laws or regulations, or, subject to the terms of the License Agreement, if Sato, its affiliates and sublicensees do not conduct any material development or commercialization activities of a Licensed Product in Japan for a certain period of time.

Huadong License and Collaboration Agreement

In August 2023, we entered into a license and collaboration agreement (Huadong Agreement) with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (Huadong), a wholly owned subsidiary of Huadong Medicine Co., Ltd., whereby Pursuant to the terms of the agreement, we granted to Huadong an exclusive, sublicensable (under certain circumstances) license under certain patent rights and know-how controlled by us for Huadong to develop, conduct medical affairs activities for, manufacture, commercialize and otherwise exploit both ZORYVE cream and ZORYVE foam (the Huadong Licensed Products) for all therapeutic uses for certain dermatological indications (the Field) in Greater China (mainland China, Hong Kong, Macau and Taiwan) and Southeast Asia (Indonesia, Singapore, The Philippines, Thailand, Myanmar, Brunei, Cambodia, Laos, Malaysia, and Vietnam) (the Huadong Territories).

The License Agreement sets forth each party's respective obligations with respect to the development, medical affairs activities, manufacture and supply, and commercialization of the Huadong Licensed Products. Pursuant to the terms of the License Agreement, Huadong will, at its expense, develop, obtain regulatory approval for, commercialize and conduct medical affairs activities related to the Huadong Licensed Products in the Field in the Huadong Territory, subject to certain of our approval and oversight rights. We will retain exclusive rights for the development, manufacture and commercialization of topical roflumilast outside the Huadong Territories.

Pursuant to the terms of the License Agreement, we received a net payment of $27.0 million in September 2023, which consisted of a $30.0 million upfront payment less the applicable tax withholding obligation in China of $3.0 million. In addition, we received payments of $3.0 million and $2.0 million in March 2024 and December 2024, respectively, related to the achievement of a development and regulatory milestones. We may also potentially receive additional payments (i) up to an aggregate amount of $19.0 million upon the achievement of certain development and regulatory milestones and (ii) up to an aggregate amount of $40.3 million upon the achievement of certain sales milestones. In addition, on a Licensed Product-by-Licensed Product and country or region-by-country or region basis, commencing from the first commercial sale of such Licensed Product in such country or region until the latest of (i) the expiration of the last valid claim in the intellectual property rights licensed by us to Huadong under the License Agreement covering such Licensed Product in such country or region, (ii) the expiration of regulatory exclusivity for such Licensed Product in such country or region, or (iii) ten years after the first commercial

sale of such Licensed Product in such country or region (the Royalty Term), we will receive low double-digit to high-teen double-digit percentage royalties on Huadong's, its affiliates' and sublicensees' total net sales, subject to certain royalty reductions.

The term of the License Agreement continues until, on a Licensed Product-by-Licensed Product and country or region-by-country or region basis, the expiration of the Royalty Term. The License Agreement may be terminated by either party in its entirety if the other party commits a material breach, subject to a cure period, or if the other party becomes insolvent. Huadong may terminate the License Agreement at-will in its entirety upon 90 days' written notice. Unless unenforceable under applicable law, we may terminate the License Agreement in its entirety if Huadong, its affiliate or sublicensee contests or assists a third party in contesting the scope, validity or enforceability of any patent or patent application licensed by us to Huadong. We may also terminate the License Agreement if Huadong (a) is convicted in a final and non-appealable judgment of a violation of any anti-corruption, anti-money laundering, sanctions or export or import control laws or regulations or (b) any director, officer, employee, agent, affiliate, sublicensee or subcontractor of Huadong is convicted in a final and non-appealable judgment of a violation of any anti-corruption, anti-money laundering, sanctions or export or import control laws or regulations in relation to the performance of the License Agreement or, subject to the terms of the License Agreement, if Huadong, its affiliates and sublicensees do not conduct any material development or commercialization activities of a Licensed Product in the Territory for a certain period of time.

See Note 7 to the consolidated financial statements.

AstraZeneca

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

We paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of our Series B convertible preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product. We also paid AstraZeneca $7.5 million upon ZORYVE cream's FDA approval of ZORYVE cream 0.3% and have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $5.0 million upon the achievement of specific regulatory approval milestones with respect to the AZ-Licensed Products. We paid AstraZeneca $5.0 million upon achievement of $100.0 million in worldwide net sales and have agreed to make an additional payment of $10.0 million when the company achieves $250.0 million in worldwide net sales. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates', and our sublicensees' net sales of such AZ-Licensed Products, subject to specified reductions, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. We began making quarterly royalty payments in the first quarter of 2023.

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

Jiangsu Hengrui Medicine Co., Ltd

In January 2018, we entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd, or Hengrui, whereby Hengrui granted us an exclusive option to obtain certain exclusive rights to research, develop, and commercialize products containing the compound designated by Hengrui as ivarmacitinib, a potent and selective JAK1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions, or the Field, in the United States, Japan, and the EU (including for clarity the United Kingdom), or the Territory.

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

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

We made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui License Agreement option and license agreement. We also made a $1.5 million cash payment in connection with the exercise of our exclusive option. In addition, we have agreed to make cash payments of up to an aggregate of $20.5 million upon our achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $200.0 million in sales-based milestones based on achieving certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products we commercialize under the agreement, we will pay tiered royalties to Hengrui on net sales of each licensed product by us, or our affiliates, or our sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the later of (1) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, we are obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income we receive from sublicensees of our rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

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

In June 2022, we entered into a side letter agreement with Hengrui and one of its subsidiaries to extend certain rights and obligations under the Hengrui License Agreement to the subsidiary under specified circumstances, including a change of control of such subsidiary. See Note 7 to the consolidated financial statements for additional information.

Government Regulation

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

U.S. Drug Development Process

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

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

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves nonclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction

of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

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

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

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

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

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

establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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

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

FDA Review and Approval Process

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

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

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

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will generally inspect the facility or the facilities at which the drug is manufactured to ensure the facility is compliant with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs.

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

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

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

Pediatric Information

The Pediatric Research Equity Act (PREA) as amended, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required clinical assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of required pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. In addition, the Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six month extension of any exclusivity—patent or nonpatent—for a drug, if a sponsor conducts clinical trials in children in response to a written

request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Expedited Development and Review Programs

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

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

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

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

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

Orphan drug designation and exclusivity

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

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

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

Post-Approval Requirements

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

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

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning, or other safety information about the product;
- fines, warning letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension, or revocation of product approvals;

- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

The Hatch-Waxman Act

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

Orange Book Listing

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

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

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

decision in the infringement case that is favorable to the applicant, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Hatch-Waxman Exclusivity

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

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

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

Other Healthcare Laws

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

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

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

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payer knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to commit a violation.

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

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

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

Formulary Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any new therapeutic product candidate. Sales in the United States will depend in part on the availability of sufficient formulary coverage and adequate reimbursement from third-party managed care organizations and private health insurers and government health payers such as Medicare, Medicaid, TRICARE, and the Veterans Administration. The ability for manufacturers to secure coverage for therapeutic product candidates can be subject to significant formulary restrictions or denial by payers.

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

A drug company's ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, and other organizations. Even if one or more products are

successfully brought to the market, these products may not be considered cost-effective, and the amount reimbursed for such products may be insufficient to allow them to be sold on a competitive basis. Increasingly, third-party payers who reimburse patients or healthcare providers, such as government and private insurers, are requiring that drug companies provide them rebates off list prices, and are seeking to reduce their prices to secure coverage.

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

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

Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payer to payer.

U.S. Healthcare Reform

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

Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in

effect in its current form. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market, and sell any products we may develop.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was enacted into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price increase disclosure, and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations. Additionally, health reform initiatives may arise in the future, particularly as a result of the 2024 presidential election.

Data Privacy and Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital Resources and Employees

As of December 31, 2024, we had 342 full-time employees. Of these full-time employees, three have an M.D., and five are Nurse Practitioners or Physician Assistants. From time to time, we also retain independent

contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

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

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

Financial Information About Segments

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

About Arcutis Biotherapeutics

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

Available Information

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

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

Item 1A. RISK FACTORS

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

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

We are a commercial-stage biopharmaceutical company with three products approved for commercial sale. We have incurred significant losses since our inception and could continue to incur losses, which, together with our limited history as a commercial-stage company, makes it difficult to assess our future viability.

We are a commercial-stage biopharmaceutical company with three products approved for commercial sale. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have a limited history as a commercial-stage company 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 include organizing and staffing our company, business planning, raising capital, identifying potential product candidates, establishing licensing arrangements, undertaking various research and nonclinical studies, conducting clinical trials, establishing manufacturing and supply operations, and preparing for and launching commercialization activities. We have incurred losses in each year since our inception in June 2016. Our net loss for the year ended December 31, 2024 was approximately $140.0 million. As of December 31, 2024, we had an accumulated deficit of $1,121.9 million. We commercially launched our first product, ZORYVE cream 0.3%, in August 2022, our second product, ZORYVE foam, in late January 2024, and our third product, ZORYVE cream 0.15%, in July 2024. We expect to continue to incur losses until our revenue from product sales of ZORYVE and any other approved products exceeds expenses, which may never occur. We may never achieve profitability and, even if we do, we may not be able to sustain or increase our profitability. We will continue to incur research and development and other expenses related to our ongoing operations, our commercialization efforts, and the development of our product candidates. Our prior losses, combined with anticipated future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives.

Due to the ongoing commercialization of products approved for commercial sale, and our development strategy and continued development of our pipeline of product candidates through clinical trials, our capital requirements are difficult to predict and may change. We may require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital if or when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate certain operations or efforts.

We expect to continue to expend substantial resources in connection with our commercialization efforts, the development of our current product candidates, the maintenance and expansion of our business operations and capabilities, and the development or acquisition of additional product candidates. These expenditures will include costs associated with marketing and selling any products approved for sale, including ZORYVE, conducting non-clinical studies and clinical trials, obtaining regulatory approvals, securing manufacturing and supply of product candidates, costs associated with in-licensing dermatology assets consistent with our core strategy, and other unanticipated costs. Because the outcome of any nonclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any of our product candidates. Similarly, due to the complexities of our recent transition to a commercial-stage company, it is challenging to estimate the actual amounts necessary to successfully commercialize any products approved for sale. Our operating expenses and capital requirements are difficult to predict, depend on many factors and are affected by, and are subject to assumptions regarding, among others:

- the timing, receipt, and amount of sales of any current and future products, including the success of our commercialization efforts involving ZORYVE;
- market acceptance of our current and future products, including ZORYVE, and the impact of competing products;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for any current or future products;
- our ability to successfully execute on our business plan and our internal projections and estimates of costs and execution timing;
- the scope, progress, results, and costs of developing product candidates and conducting nonclinical studies and clinical trials, including in connection with our current product candidates;
- suspensions or delays in enrollment of our ongoing and future clinical trials, issues with data collection, or changes to the number of subjects we decide to enroll in our clinical trials, including as a result of competing trials or otherwise;
- the number and scope of clinical programs we decide to pursue, and the number and characteristics of any product candidates we develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory reviews and approvals for our product candidates;

- the cost of manufacturing any current and future products and product candidates, including any products we successfully commercialize and the costs associated with building out our supply chain;
- the cost of commercialization activities for any current and future products that are approved for sale, including marketing, sales, and distribution costs, and any discounts or rebates to obtain access;
- 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 impact of any acquisitions or similar transactions or partnerships;
- the costs related to milestone and royalty payments due to AstraZeneca, Hengrui, the former owners of Ducentis, which we acquired in September 2022, or any future collaboration or licensing partners upon the achievement of negotiated milestones;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio.

As of December 31, 2024, we had capital resources consisting of cash, cash equivalents, and marketable securities of $228.0 million. In addition, as of December 31, 2024, we had $100.0 million outstanding under our loan and security agreement, or the Loan Agreement, with SLR Investment Corp., or SLR, and the lenders party thereto. If our capital resources are insufficient to satisfy our requirements, we may need to fund our operations through the sale of our equity securities, accessing or incurring additional debt, entering into licensing or collaboration agreements with partners, grants, or other sources of financing. 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.

Any such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. There can be no assurance that sufficient funds will be available to us at all or on attractive terms when needed from these sources. If we are unable to obtain additional funding from these or other sources when needed, it may be necessary to significantly reduce our current rate of spending through, among other things, reductions in staff and delaying, scaling back, or stopping certain research and development programs, nonclinical studies, clinical trials or other development activities, and commercialization efforts. We may also be required to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose or grant rights to develop and market product candidates 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 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:

- our ability to commercialize approved products and our ability to receive approval and commercialize our product candidates both within and outside of the United States;
- market acceptance of any current and future products and our ability to forecast demand for such products;
- the level of demand for any current and future products, which may vary significantly;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for any current or future products;
- the willingness of patients to pay out-of-pocket for any current or future products in the absence of health insurance coverage or sufficient reimbursement;
- delays in the commencement, enrollment, and the timing of clinical testing for our product candidates, in light of competing trials or otherwise;

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development, or failure to obtain such approvals;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time and are subject inflation and other drivers;
- the cost of manufacturing any current and future products and product candidates, which may vary depending on U.S. FDA guidelines and requirements, and the quantity of production;
- our ability to obtain funding to develop our products and product candidates and operate our business;
- 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;
- potential side effects of any current and future products and product candidates that could delay or prevent commercialization or cause an approved product to be taken off the market;
- our dependency on Contract Research Organizations (CROs) to help manage our clinical trials, and third-party manufacturers for adequate supply or manufacturing capabilities;
- our ability to establish and maintain collaborations, licensing, or other arrangements;
- our ability to maintain and enforce our intellectual property position;
- costs related to and outcomes of potential litigation, potential government investigations, or other disputes;
- 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 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 approved product and product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and there can be no assurance as to its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described 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 should not be taken as indicative of our ability to grow our business.

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

As of December 31, 2024, we had $100.0 million outstanding under our Loan Agreement. On August 9, 2024, we entered into a second amendment to the Loan Agreement, pursuant to which the terms were revised to, among others, permit us to make an optional partial prepayment of term loans outstanding during the period commencing on October 7, 2024 and ending on December 15, 2024, subject to a 1.0% prepayment penalty (the 2024 Partial Prepayment). On October 8, 2024, we made a 2024 Partial Prepayment of $100.0 million. In connection with the 2024 Partial Prepayment, we are obligated to pay a prepayment penalty of $1.0 million by June 30, 2026 and a final fee of $6.95 million, representing the final fee applicable to the amount of the 2024 Partial Prepayment, on January 1, 2027. As a result of such 2024 Partial Prepayment, subject to us generating a minimum net product revenue for the trailing six-month period ending as of the month prior to the borrowing date equal to 80% of our projected net product revenue as set forth in our annual plan for the respective period, we will be able to draw down a tranche C-1 term loan of up to $50.0 million and a tranche C-2 term loan of up to $50.0 million. The tranche C-1 term loan availability will expire on March 31, 2026 and the tranche C-2 term loan availability will expire on June 30, 2026. As security for the obligations under the Loan Agreement, we granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of our assets, including our intellectual property, subject to certain exceptions.

The Loan Agreement contains a number of representations and warranties and affirmative and restrictive covenants, including financial covenants, and the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry, or take future actions. The Loan Agreement includes a financial covenant whereby we must generate minimum net product revenue equal to 75% of our projected net product revenue as set forth in our annual plan for the respective period, tested on a trailing six-month basis as of the end of each month. Each annual plan shall be approved by our board of directors and SLR, in its capacity as collateral agent, in its reasonable discretion. Any failure by us to deliver such annual plan on or before December 15 of the prior year shall be an immediate event of default.

If the debt under the Loan Agreement were accelerated due to an event of default or otherwise, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition. If we do not have or are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern. Moreover, regardless of a potential event of default, the debt under the Loan Agreement matures and is due on August 1, 2029. As a result, we may need to refinance or secure separate financing in order to repay amounts outstanding when due, however, no assurance can be given that an extension will be granted, that we will be able to renegotiate the terms of the agreement with the lender, or that we will be able to secure separate debt or equity financing on favorable terms, if at all.

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

We are a large accelerated filer and no longer qualify as a "smaller reporting company," which requires additional compliance initiatives and heightened disclosure and reporting requirements.

We are subject to Section 404 of the Sarbanes-Oxley Act, which generally requires a company's management to report upon the effectiveness of internal control over financial reporting and an independent registered public accounting firm to attest to the effectiveness of internal control over financial reporting in annual reports on Form 10-K. However, during any period in which we qualified as a smaller reporting company, we were not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. As of June 30, 2024, the market value of our ordinary shares held by non-affiliates exceeded $700.0 million. As a result, we became a large accelerated filer, effective December 31, 2024. As a result

of this transition, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm with this Annual Report on Form 10-K for the fiscal year ending December 31, 2024. To prepare for compliance with Section 404, we engaged in a process to document and evaluate our internal control over financial reporting, which was both costly and challenging. In this regard, we dedicated internal resources, engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting. We have continued steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. As a result of this transition, we are subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us during the period in which we qualified as a smaller reporting company, and we are not able to take advantage of certain scaled disclosures available to smaller reporting companies. Any failure to comply with the increased disclosure and reporting requirements could have an adverse effect on our business, financial condition and results of operations.

Changes in corporate governance policies and practices may impact our business.

As a public company, we are subject to corporate governance, public disclosure and compliance practices, which continue to evolve based upon continuing legislative action, SEC rulemaking, stockholder activism and policy positions taken by large institutional stockholders and proxy advisors. As a result, the number of rules, regulations and standards applicable to us may become more burdensome to comply with, could increase scrutiny of our practices and policies by these or other groups and increase our legal and financial compliance costs and the amount of time management must devote to governance and compliance activities. For example, the SEC has recently adopted rules requiring that issuers provide significantly increased disclosures concerning cybersecurity matters and requiring public companies to adopt more stringent executive compensation clawback policies.

Risks Related to Development and Commercialization

The sales, marketing, and distribution of ZORYVE or any future approved products may be unsuccessful or less successful than anticipated.

We began commercializing our first product in the United States in August 2022. As a company, we had no prior experience commercializing a product. The success of our commercialization efforts for ZORYVE and any future approved products is difficult to predict and subject to the effective execution of our business plan, including, among others, the continued development of our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities.

For example, we have established an internal commercial infrastructure as well as a dermatologist-focused sales and distribution infrastructure to market ZORYVE and our product candidates in North America, and have completed hiring in areas to support commercialization, including in sales management, sales representatives, marketing, access and reimbursement, sales support, and distribution. There are significant expenses and risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure in the development of these capabilities could delay or negatively affect the success of our commercialization efforts and our business. For example, the commercialization of ZORYVE may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses.

If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if the commercialization of ZORYVE or any future approved products does not develop as planned, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

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

We currently have three products approved for commercial sale: ZORYVE cream 0.3%, a potent PDE4 inhibitor topical cream approved by the FDA on July 29, 2022, for the treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older (subsequently expanded to patients 6 years of age and older); ZORYVE foam, a potent PDE4 inhibitor topical foam approved by the FDA on December 15, 2023, for the treatment of seborrheic dermatitis in individuals aged 9 years and older; and ZORYVE cream 0.15%, a potent PDE4 inhibitor topical cream for the treatment of atopic dermatitis in adults and pediatric patients 6 years of age and older, which was approved on July 9, 2024. Our product candidate portfolio includes ZORYVE foam for the treatment of scalp and body psoriasis, ZORYVE cream 0.05% for the treatment of atopic dermatitis in patients ages 2 to 5,

ARQ-255, a potent and highly selective topical JAK1 inhibitor under development for the treatment of alopecia areata, ARQ-252, an alternative formulation of our topical JAK1 inhibitor under development for the treatment of chronic hand eczema and vitiligo, and ARQ-234, a CD200R fusion protein for the treatment of moderate-to-severe atopic dermatitis. We currently do not have drug discovery efforts, and we have no intention to develop a drug discovery capability. 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 commercialization of ZORYVE and the successful development, regulatory approval, and commercialization of other product candidates. We expect to conduct most of our clinical trials in the United States and Canada, with limited reliance on Australia, the Caribbean, and the European Union for clinical trials subjects. We currently anticipate seeking additional regulatory approvals in the United States and Canada, but may in the future be subject to additional foreign regulatory authorities and may out-license our product candidates or approved products, if any, in additional foreign markets. In the future, we may also become dependent on other product candidates that we may develop, acquire, or in-license. The commercial success of ZORYVE and the clinical and commercial success of other product candidates will depend on a number of factors, including the following:

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

Furthermore, because ZORYVE and each of our product candidates targets one or more indications in the medical dermatology field, if ZORYVE or 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 or 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 ZORYVE or our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of ZORYVE or our product candidates or any future product candidates to continue our business.

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

Notwithstanding the marketing approval of ZORYVE and any other product candidates, such products may fail to gain sufficient market acceptance by physicians, patients, third-party payers, and others in the medical community. If ZORYVE or our other 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 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;
- the prevalence and severity of any side effects and the difficulty of, or costs associated with, resolving such side effects;
- the content of the approved product label, including any limitations or warnings contained in the labeling approved by FDA or other applicable foreign regulatory authorities;
- any restrictions on the use of our products;
- the effectiveness of our sales and marketing efforts;
- the strength of our marketing and distribution support;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments and over-the-counter (OTC) treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies over existing therapies;
- the availability of coverage and adequate reimbursement from private third-party payers and governmental healthcare programs, such as Medicare and Medicaid;
- the willingness of patients to pay out-of-pocket in the absence of health insurance coverage or sufficient reimbursement; and
- utilization controls imposed by third-party payers, such as prior authorizations and step edits.

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

If we are unable to achieve and maintain third-party payer coverage and adequate levels of reimbursement for ZORYVE or 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.

For ZORYVE and 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 payers. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers 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 payers 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 ZORYVE or any of our product candidates fail to demonstrate attractive efficacy and safety 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 ZORYVE and certain of our product candidates will depend significantly on access to third-party payers' drug formularies, or lists of medications for which third-party payers provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and

reimbursement for drug products can differ significantly from payer to payer. 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 ZORYVE and our product candidates to each payer 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 ZORYVE and 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.

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 and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete nonclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

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

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

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

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

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

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

There is significant regulatory risk involving our products and product candidates, and we cannot provide assurance that any of our products will gain expanded labels or that our product candidates will obtain regulatory approval for commercialization as expected, or at all. The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market expanded indications of our products or any product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions, including pricing approval in the EU.

The FDA or any foreign regulatory authorities can delay, limit, or deny approval of expanded labels for our products or 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;
- the FDA or other relevant foreign regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products candidates outweigh their safety risks or that there is an acceptable risk-benefit profile;
- the results of our clinical trials may not meet the level of statistical significance or clinical meaningfulness required by the FDA or other relevant foreign regulatory authorities for marketing approval;
- the FDA's or the applicable foreign regulatory authority's requirement for additional nonclinical studies or clinical trials which would increase our costs and prolong our development timelines;

- the FDA or other relevant foreign regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of any product or product candidate, or may require that we conduct additional studies;
- the FDA or other relevant foreign regulatory authorities may not accept data generated from our clinical trial sites;
- the CROs that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact our clinical trials and ability to obtain market approvals;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant foreign regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant foreign regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- the FDA or other relevant foreign regulatory authorities may require development of a Risk Evaluation and Mitigation Strategy (REMS), or its equivalent, as a condition of approval;
- the FDA or other relevant foreign regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant foreign regulatory authorities may find the chemistry, manufacturing, and controls data insufficient to support the quality of our product candidates;
- the FDA or other relevant foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers;
- the FDA or other relevant foreign regulatory authorities may change their approval policies or adopt new regulations;
- the FDA's or the applicable foreign regulatory authority's non-approval of the formulation, dosing, labeling, or specifications;
- the FDA's or the applicable foreign regulatory authority's failure to approve the manufacturing processes of third-party manufacturers upon which we rely or the failure of the facilities of our third-party manufacturers to maintain a compliance status acceptable to the FDA or the applicable foreign regulatory authority; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

The use of patient reported outcome instruments in our clinical trials and the inclusion of such data in any product labeling depends on, but is not limited to, the FDA's review of the following:

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

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

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

We may not be able to initiate, timely enroll or continue clinical trials if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Patient enrollment is affected by a variety of factors, including but not limited to:

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

For example, it may be more challenging to identify and enroll certain patient populations or groups, such as pediatric patients, and we experienced enrollment delays in our INTEGUMENT-PED pediatric trial. In addition, our competitors have previously conducted, are currently conducting, and may in the future conduct clinical trials for product candidates that treat the same indications as our product candidates, and subjects who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

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

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

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

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

Additionally, following marketing approval of any of our product candidates, we or others may identify undesirable side effects caused by such products, which could result in a number of potentially significant negative consequences, including:

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

Any of these events could prevent us from achieving or maintaining market acceptance and could significantly harm our business, results of operations, and prospects.

As a company, we have obtained marketing approval for only three products and we may be unable to successfully obtain marketing approval in a timely manner, or at all, for any of our other product candidates.

Obtaining marketing approval or an additional indication for a product candidate is a complicated process. As a company, we have obtained approval for ZORYVE cream 0.3% for the topical treatment of plaque psoriasis in

adults and pediatric patients 6 years of age and older in the United States and Canada, approval for ZORYVE foam for the topical treatment of seborrheic dermatitis in adults and pediatric patients 9 years of age and older in the United States and Canada, as well as approval for ZORYVE cream 0.15% for the topical treatment of atopic dermatitis in adults and pediatric patients 6 years of age and older in the United States. Due to the complexities of the marketing approval process, this process and the related activities may require more time and/or cost more than we anticipate, and we may be unable to successfully complete such process and related activities for any of our product candidates. 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 file for substantive review any NDAs or sNDAs that we submit for our product candidates or may conclude after review of our applications that they are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept for filing or approve any applications for our product candidates, it may require that we conduct additional clinical, nonclinical, or manufacturing validation studies and submit that data before it will reconsider such applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA, sNDA or 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 any NDAs or sNDAs that we may submit. 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.

We may choose not to continue developing or commercializing ZORYVE or any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for ZORYVE, and our 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, and changes in, or our 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 seek to market products in countries other than the United States or Canada, we will need to comply with the regulations of each country in which we seek to market our products.

No product or product candidate is currently approved for sale by any government authority in any jurisdiction other than the United States and Canada. 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, such as in the United States or Canada, 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 and share purchase agreement with Ducentis Biotherapeutics obligates us to make certain milestone and royalty payments, some of which have been or will be triggered prior to commercialization of the applicable product candidates.

Certain of the milestone payments payable by us to AstraZeneca and Hengrui under our licensing agreements are due upon events that will occur prior to our planned commercialization of the applicable product or product candidate. Accordingly, we have been and will in the future be required to make such payments prior to the generation of any revenue from sales of the respective product or product candidate.

For example, we paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of ZORYVE cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product (as defined below). In addition, we paid AstraZeneca $7.5 million in August 2022 upon FDA approval to commercialize ZORYVE cream 0.3% in the United States and $5.0 million in October 2024 upon achievement of $100.0 million in worldwide net sales. We are required to make additional cash payments to

AstraZeneca of up to an aggregate of $5.0 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 $10.0 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 covering ivarmactinib 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 ivarmacitinib 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 sub-teens to the low-thirties, 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.

In addition, pursuant to the share purchase agreement with Ducentis, we agreed to make certain contingent payments, which may become payable upon the achievement of certain development, regulatory, and commercial milestones. We estimate that these contingent payments may be up to an aggregate of approximately $400 million, although the actual amount may differ depending on whether the applicable milestones are achieved. In addition, if applicable, we will make payments amounting to a mid-single-digit percentage of any annual net sales of Ducentis's products exceeding $1.5 billion. As of December 31, 2024, none of the milestones were probable of achievement and, accordingly, no amounts have been recognized in the accompanying consolidated financial statements with respect to these contingent payments.

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 agreements noted above with AstraZeneca, Hengrui and Ducentis, 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 we will face significant competition for ZORYVE and for other product candidates, if approved, from other approved therapies or drugs that become available in the future for the treatment of our target indications. ZORYVE and 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 ZORYVE and our product candidates, a less effective branded, generic, or OTC product may be more quickly adopted by physicians and patients than ZORYVE or our product candidates based upon cost or convenience.

ZORYVE and 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 these markets, 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 ZORYVE or our product candidates and contribute to downward pressure on the pricing of ZORYVE or 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 ZORYVE or our product candidates for the treatment of psoriasis, atopic dermatitis, chronic hand eczema, vitiligo, and alopecia areata, including a potential generic version of ZORYVE cream.

For psoriasis, our primary competitors include injected biologic therapies such as Humira, marketed by AbbVie Inc. and Eisai Co., Ltd., and Enbrel, marketed by Amgen Inc.; Pfizer Inc., and Takeda Pharmaceutical Company Limited; non-injectable systemic therapies used to treat plaque psoriasis such as Otezla, marketed by Amgen Inc., and Sotyktu, marketed by Bristol Myers Squibb; topical therapies such as Vtama, marketed by Organon & Co.; 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.

For atopic dermatitis, our primary competitors include topical therapies such as Eucrisa, marketed by Pfizer Inc.; Opzelura, marketed by Incyte Corporation, Vtama, marketed by Organon & Co., and generic and branded versions of low to mid-potency steroids such as hydrocortisone or triamcinolone. In the moderate-to-severe setting, the injected biologic therapies Dupixent, marketed by Regeneron Pharmaceuticals, Inc; Adbry, marketed by LEO Pharma; and Ebglyss, marketed by Eli Lilly & Co. Non-injectable systemic therapies RINVOQ and CIBINQO are also approved in moderate-to-severe atopic dermatitis. In addition, there are several prescription product candidates under development that could potentially be used to treat atopic dermatitis and compete with ZORYVE cream and ARQ-234, including but not limited to: topical difamilast ointment, under development by Medimetriks/Otsuka Pharma, injectable rocatinlimab, under development by Amgen, and injectable amlitelimab, under development by Sanofi.

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, especially Olumiant (baricitinib), marketed by Eli Lilly and Company, and Litfulo (ritlecitinib), marketed by Pfizer, inc., both oral JAK inhibitors, and the only FDA-approved treatments for alopecia areata. 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 deuruxolitinib (CTP-543), under development by Sun Pharmaceuticals.

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 Anzupgo (delgocitinib), under development by LEO Pharma A/S, is currently under review by the FDA, and is approved in Europe by the EMA.

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; the topical JAK inhibitor Opzelura, marketed by Incyte Corporation; 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-255, including but not limited to: oral ritlecitinib Litfulo under development by Pfizer Inc.

Many of our existing or potential competitors have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our

competitors. Competition may reduce the number and types of subjects available to us to participate in clinical trials, because some subjects who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

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

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

- develop and commercialize therapies that have a competitive product profile or are superior to other products in the market;
- demonstrate through our clinical trials that ZORYVE and 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, ZORYVE, and product candidates;
- obtain required regulatory approvals, including approvals to market our product candidates in ways that are differentiated from existing and future therapies and OTC products and treatments;
- successfully commercialize ZORYVE and our product candidates, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payers; 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 as well as the reimbursement and quality of coverage for ZORYVE or 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. Furthermore, upon the expiration or loss of any patent protection for any of our approved products, or upon the "at-risk" launch, despite pending patent infringement litigation against the generic product or its equivalent, by a generic competitor of a generic version of any of our approved products, which may be sold at significantly lower prices than our products, we could lose a significant portion of sales of that product in a short period of time, which would adversely affect our business, financial condition, operating results and prospects.

Risks Related to Our Business and Operations

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

As of December 31, 2024, we had 342 full-time employees. In order to effectively execute our growth strategy, we may need to identify, recruit, retain, incentivize, and integrate additional employees in order to expand our ability to:

- drive adoption, demand and reimbursement for ZORYVE and any future products and indications approved for marketing;
- establish and maintain relationships with development and commercialization partners;
- manage our clinical trials effectively;
- manage our internal development and operational efforts effectively, including in respect of product candidates;
- continue to improve our operational, financial, management, and regulatory compliance controls and reporting systems and procedures, particularly as we scale our organization; and
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for ZORYVE and our product candidates to commercial levels.

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

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

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

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

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

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

Our current and future collaboration arrangements may not be successful, which could adversely affect our ability to develop and commercialize future product candidates.

We have entered into a strategic collaboration and licensing agreement for topical roflumilast in Greater China and Southeast Asia with Hangzhou Zhongmei Huadong Pharmaceutical Co., a wholly owned subsidiary of Huadong Medicine Co., Ltd., a strategic collaboration and licensing agreement for topical roflumilast in Japan with Sato Pharmaceutical Co., Ltd., and a co-promotion agreement with Kowa Pharmaceuticals America, Inc. to exclusively market and promote ZORYVE to primary care practitioners and pediatricians for all FDA-approved indications in the United States. In the future, we may seek additional 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. To the extent that we decide to enter into future collaboration agreements, we will face 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. The terms of any collaborations or other arrangements that we may establish may not be favorable to us. Our current and future collaborations 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, including with respect to accessing primary care and pediatric practices;
- collaborators are or may in the future be entitled to fees, royalties, profit sharing, and other consideration, which may limit or otherwise negatively impact our profit and financial performance;
- we have and could in the future grant exclusive rights to our collaborators that 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, 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 result from our collaborating with them, and in such cases, would result in us not having 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 any collaboration or other strategic transaction will achieve the expected synergies. 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 entail numerous operational and financial risks, including exposure to unknown liabilities, dependence upon the performance and discretion of counterparties that we do not control and that may underperform or fail, 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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of ZORYVE or 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 ZORYVE or 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 ZORYVE or 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 ZORYVE or 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 ZORYVE or current or any future product candidates we develop. Although we currently carry product liability insurance covering our products and product candidates, 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 we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could undermine the credibility of our operating results, harm investors' views of us and, as a result, the value of our common stock.

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

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

In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market, or other adverse consequences that would materially harm our business.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of 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, preclinical and clinical trial data, and personal information (collectively, Confidential Information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

Our information technology systems and infrastructure, and those of our current and any future service providers, strategic partners, and other collaborators, contractors and consultants, are vulnerable to attack, damage and interruption from computer viruses and malware (e.g., ransomware), misconfigurations, “bugs” or other vulnerabilities, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks or cyber-intrusions over the Internet, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks and, sophisticated nation-state and nation-state-supported actors. While our controls and procedures help enable us to protect from or respond to cybersecurity threats, there can be no assurance that these controls and procedures will be adequate to protect us from any cyber incident. The threats are always evolving and, in the future, our existing controls and procedures may become inadequate and may require additional resources or enhanced systems.

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. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to

date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. It could also expose us to risks, including an inability to provide our services and fulfill contractual demands, and could cause management distraction and the obligation to devote significant financial and other resources to mitigate such problems, which would increase our future information security costs, including through organizational changes, deploying additional personnel, reinforcing administrative, physical and technical safeguards, further training of employees, changing third-party vendor control practices and engaging third-party subject matter experts and consultants and reduce the demand for our technology and services.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted. In addition, the prevalent use of mobile devices and employees and contractors working from home and/or remote locations that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, and security vulnerabilities could be significant and are likely to increase in the future. These costs include, but are not limited to, retaining the services of cybersecurity providers; compliance costs arising out of existing and future cybersecurity, data protection and privacy laws and regulations; and costs related to maintaining redundant networks, data backups and other damage-mitigation measures.

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. Further, while we maintain liability coverage, we cannot be certain that our coverage is adequate for all material incidents or losses incurred. Any security compromise affecting us, our service providers, strategic partners, other contractors, consultants, or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. If such an event were to occur, it could result in a material disruption of our product development programs and commercial operations. 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 confidential, proprietary, or personal information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. 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. Further, our existing insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed.

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

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal, and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts

governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act (collectively, the CCPA) requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the Federal Trade Commission (the "FTC") and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

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

Failure to comply with anti-corruption and anti-money laundering laws, including the FCPA and similar laws associated with our activities outside of the United States, as well as export and import controls, customs, and economic and trade sanctions laws, could subject us to penalties and other adverse consequences.

We are subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery or anti-corruption laws, regulations and rules in the United States and other countries in which we and our partners operate. These laws generally prohibit companies and their employees and third-party intermediaries from corruptly promising, authorizing, offering, or providing, directly or indirectly, improper payments of anything of value to government officials, political parties, and private-sector recipients for the purpose of obtaining or retaining business, directing business to any person, or securing any improper advantage. Certain laws also prohibit soliciting or receiving bribes or improper payments. In many foreign countries, including countries in which we or our partners may conduct business, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. As our business expands and we engage with international partners through collaboration, licensing and other agreements, the applicability of the FCPA and other anti-bribery laws to our operations, and the potential risk of violations of such laws, will increase. We face significant risks if we or any of our directors, officers, employees, agents or other partners or representatives fail to comply with these laws and governmental authorities in the United States and elsewhere could seek to impose substantial civil and/or criminal fines and penalties which could have a material adverse effect on our business, reputation, financial condition, and results of operations.

Our employees, contractors, and agents, and companies to which we outsource or license certain activities, may take actions in violation of our internal policies or applicable law. Any such violation could have an adverse effect on our reputation, business, results of operations, and prospects. Further, any violation of the FCPA, other applicable anti-corruption laws, or anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions, any of which could have a materially adverse effect on our reputation, business, results of operations, and prospects. In addition, responding to any enforcement action may result in a significant diversion of management's attention and resources and significant defense costs and other professional fees.

In addition, we may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our approved products, or our failure to obtain any required import or export authorization for our approved products, when applicable, could harm our business and adversely affect our growth. We could be subject to future enforcement action with respect to compliance with governmental export and import controls, customs laws, and economic and trade sanctions laws, and such enforcement could result in penalties, costs, and restrictions on export privileges that could have an adverse effect on our business, reputation, financial condition, and results of operations.

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

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

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

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

Risks Related to Our Reliance on Third Parties

We rely on third-party manufacturers to manufacture nonclinical, clinical and commercial supplies of ZORYVE and our product candidates. The loss of these manufacturers or their sub-suppliers, or their failure to provide us with sufficient quantities at acceptable quality levels, or at all, would materially and adversely affect our business.

We do not currently have the infrastructure or capability internally to manufacture supplies of ZORYVE or our product candidates or the materials necessary to produce ZORYVE or our product candidates for use in the conduct of our nonclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture ZORYVE or any of our product candidates on a nonclinical, clinical or commercial scale. Instead, we currently rely on single source third-party manufacturers to manufacture nonclinical, clinical, and commercial supplies of ZORYVE and intend to rely on third-party manufacturers for any future approved product. As an early commercial-stage company with a limited history of product sales, the quantity and quality of deliveries received to date may not represent what will be required to meet our future commercial requirements.

We and the manufacturers of our products rely on suppliers of raw materials and components used in the production of our products. Some of these materials are available from only one source. If there is a disruption beyond our planned safety stock to one or more of our third-party suppliers' relevant operations, we will have no other means of producing ZORYVE or our product candidates until they restore the affected facilities or they procure alternative manufacturing facilities or sources of supply. Our ability to commercialize ZORYVE or to progress our nonclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory, or reputational issues. Additionally, any damage to or destruction of our third-party manufacturer's facilities or equipment may significantly impair our ability to manufacture ZORYVE or our product candidates on a timely basis.

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

In addition, to manufacture our product candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers may need to increase manufacturing capacity and, in some cases, we are securing alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If either we or our manufacturers are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the commercial launch of our lead product candidates or any future product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved, or impact the costs of procuring sufficient demand of materials or costs of manufacturing the product. Additionally, the imposition of tariffs and other orders or restrictions impacting trade could adversely impact our business, including by increasing or otherwise impacting the costs and expenses we incur in connection with our operations and supply chain.

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 of ZORYVE or our product candidates.

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

If a third-party manufacturer with whom we contract is unable to comply with applicable laws and regulations including cGMPs, we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

We rely on third parties to conduct our nonclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

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

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

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

Risks Related to Intellectual Property

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

Our success with respect to ZORYVE and 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 ZORYVE and 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, ZORYVE and 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 ZORYVE or our product candidates, or may not provide us with sufficient protection for ZORYVE or our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. For example, even if patent protection for our product candidates is successfully obtained, we may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may also challenge the scope, validity, or enforceability of the patents to which we have right in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively. On February 14, 2024, we received a Paragraph IV Notice Letter advising that Padagis Israel Pharmaceuticals Ltd. (Padagis) had submitted an ANDA to the FDA seeking authorization to manufacture, use, sell, and import a generic version of ZORYVE cream. On July 16, 2024 and September 12, 2024, we received additional Paragraph IV Notice Letters from Padagis, Padagis' Paragraph IV certifications stated that our patents listed in the FDA's Orange Book will not be infringed by Padagis' proposed product, are invalid and/or are unenforceable. We filed suit against Padagis in the U.S. District Court for the District of Delaware on March 27, 2024 for infringement of certain of our patents and amended our complaint on July 19, 2024 to add additional patents to our infringement allegations. On August 2, 2024, Padagis responded to the first amended complaint, denying infringement and asserting counterclaims seeking a declaratory judgment that the asserted patents are not infringed, invalid, and/or unenforceable. The court issued a scheduling order on June 10, 2024, which sets trial at the court's convenience, or around April 13-17, 2026. The complaint triggered the automatic 30-month stay of FDA approval of the ANDA, which expires on August 14, 2026, and we plan to vigorously defend our extensive intellectual property rights in ZORYVE.

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 ZORYVE or our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, ZORYVE 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 API 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. In addition to potentially being open to competition from generic versions without patent protection for ZORYVE or our product candidates, 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 ZORYVE with claims directed to, among other things, formulating roflumilast in combination with hexylene glycol and a method of treatment with a topical roflumilast formulation with an extended half-life are currently projected to expire in mid-2037, our method of treatment patent specifically for roflumilast foam in the treatment of seborrheic dermatitis is currently projected to expire in 2041, 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 December 19, 2032 and October 15, 2035 unless any PTE is granted. Additionally, an issued U.S. patent related to the composition of matter in ARQ-234 is currently projected to expire on July 14, 2038 unless any PTE is granted. Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants, and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers, and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of ZORYVE cream 0.3%, ZORYVE cream 0.15%, ZORYVE cream 0.05%, ZORYVE foam, ARQ-252, ARQ-255, ARQ-234, or any other 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 ZORYVE cream 0.3%, ZORYVE cream 0.15%, ZORYVE cream 0.05%, ZORYVE foam, ARQ-252, ARQ-255, or ARQ-234 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 ZORYVE cream 0.3%, ZORYVE cream 0.15%, ZORYVE cream 0.05%, ZORYVE foam, ARQ-252, ARQ-255, or ARQ-234. 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 ZORYVE cream 0.3%, ZORYVE cream 0.15%, ZORYVE cream 0.05%, ZORYVE foam, ARQ-252, ARQ-255, or ARQ-234.

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

In addition to infringement claims against us, if third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the U.S. Patent and Trademark Office (USPTO), to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. For example, Teva Pharmaceutical Industries Ltd. filed Oppositions with the European Patent Office against two of our European patents, European Patent Nos. EP 3634380 B1 and EP 3684334 B1, on September 20, 2024 and August 13, 2024, respectively. 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 ZORYVE cream 0.3%, ZORYVE cream 0.15%, ZORYVE Cream 0.05%, ZORYVE foam, ARQ-252, ARQ-255, or ARQ-234 can be challenged by competitors.

One or more third parties may challenge the patents covering ZORYVE cream 0.3%, ZORYVE cream 0.15%, or ZORYVE foam, or if approved by the FDA, ZORYVE foam for scalp and body psoriasis, ZORYVE cream 0.05%, ARQ-252, or ARQ-255, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third-party files an abbreviated NDA, or ANDA, for a generic drug bioequivalent to ZORYVE cream 0.3%, ZORYVE cream 0.15%, ZORYVE cream 0.05%, ZORYVE 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 from the date of receipt of the notice 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 ZORYVE or our product candidates.

On February 14, 2024, we received a Paragraph IV Notice Letter advising that Padagis had submitted an ANDA to the FDA seeking authorization to manufacture, use, sell, and import a generic version of ZORYVE 0.3%

cream. On July 16, 2024 and September 12, 2024, we received additional Paragraph IV Notice Letters from Padagis. Padagis' Paragraph IV certifications stated that our patents listed in the Orange Book will not be infringed by Padagis' proposed product, are invalid and/or are unenforceable. We filed suit against Padagis in the U.S. District Court for the District of Delaware on March 27, 2024 for infringement of certain of our patents and amended our complaint on July 19, 2024 to add additional patents to our infringement allegations. On August 2, 2024, Padagis responded to the first amended complaint, denying infringement and asserting counterclaims seeking a declaratory judgment that the asserted patents are not infringed, invalid and/or unenforceable. The court issued a scheduling order on June 10, 2024, which sets trial at the court's convenience, or around April 13-17, 2026. The complaint triggered the automatic 30-month stay of FDA approval of the ANDA, and we plan to vigorously defend our extensive intellectual property rights in ZORYVE 0.3% cream as appropriate.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term of ZORYVE or 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, ZORYVE, other product candidates, and our target indications. Our issued U.S. patents, with claims encompassing ZORYVE, directed to roflumilast formulations with reduced crystal growth and beneficial pharmacokinetic parameters and methods of treatment with a topical roflumilast formulation with an extended half-life and that decrease gastrointestinal side effects relative to oral roflumilast formulations are currently projected to expire in mid-2037. We also have a method of treatment patent specifically for roflumilast foam in the treatment of seborrheic dermatitis which expires 2041. 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 ivarmacitinib, or bisulfate and crystal forms thereof, are currently projected to expire beginning in December 2032. 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 nonclinical 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, including China and certain other developing countries, do not protect intellectual property rights, particularly those relating to biotechnology, to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in

unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unified Patent Court (UPC). As the UPC is a new court system, there is little precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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 ZORYVE or any of our product candidates, our competitors might be able to enter the market earlier than anticipated, which would harm our business.

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

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

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

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

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

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

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

We have licensed or acquired certain intellectual property rights covering ZORYVE and our current product candidates from third parties, including AstraZeneca and Hengrui. We are heavily dependent on our agreements with such third parties for ZORYVE and 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 ZORYVE or 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 ZORYVE or our product candidates or to prevent others from marketing similar products.

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

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

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

Our commercial success depends in part on our and our licensors avoiding infringement and other violations of the patents and proprietary rights of third parties. However, our research, development, and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product

candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

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

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

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

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

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

Risks Related to Government Regulation

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

Any regulatory approvals or other marketing authorizations we have or will obtain, including for ZORYVE or our product candidates that obtain approval in the future, 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 products and product candidates, such as ZORYVE, ARQ-252, ARQ-255 and ARQ-234, 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, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for ZORYVE, and if approved, our other 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 ZORYVE or 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 ZORYVE or our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters or holds on clinical trials;
- refusal by the FDA to accept new marketing applications or supplements, approve or otherwise authorize for marketing pending applications or supplements to applications filed by us or suspension or revocation of approvals or other marketing authorizations;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if renewed global

health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives) and teaching hospitals, the ownership and investment interests held by such physicians and their immediate family members;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows, or should know, it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- 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 payers, including private insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

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

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

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize ZORYVE and 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 ZORYVE or any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and ACA, as amended by the Health Care and Education Reconciliation Act, collectively the ACA, was enacted in the United States to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on the pricing of medical items and services, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the ACA of importance to ZORYVE and 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;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, resulted in reductions to Medicare payments to providers that will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022; the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years; 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; and the American Rescue Plan Act of 2021, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

The cost of prescription pharmaceuticals in the United States has long been the subject of considerable discussion in Congress and among policymakers. Recently, there have been several Congressional inquiries, as well as legislative and regulatory initiatives and executive orders designed to, among other things, bring more transparency to product pricing and reform government program reimbursement methodologies for drug products. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these

provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry and our business cannot yet be fully determined, it may be significant.

Further, members of Congress and the Biden Administration have indicated they will continue to pursue further legislative or administrative measures to control prescription drug costs, although the likelihood of such measures being adopted remains uncertain. Individual states in the United States have also enacted legislation and implementing regulations designed to control pharmaceutical product pricing, and additional states may do so. We cannot predict with certainty what impact any federal or state health reform measures will have on us, but such changes could impose new or more stringent regulatory requirements on our activities, affect the prices we may obtain, increase our discount and rebate liability, or result in reduced reimbursement for ZORYVE or our product candidates, if approved, any of which could adversely affect our business, results of operations, and financial condition.

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 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 payers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates be subject to enforcement action and we may not achieve or sustain profitability, which would adversely affect our business.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, results of operations and financial condition.

Upon commercializing ZORYVE, we started to participate in the Medicaid Drug Rebate Program, or MDRP, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require manufacturers to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries of these programs. As a condition of having federal funds being made available for covered outpatient drugs under Medicaid and Medicare Part B, a manufacturer must enroll in the MDRP. Under this program, the manufacturer must pay a rebate to state Medicaid programs for each unit of a covered outpatient drug dispensed to a Medicaid beneficiary and paid for by a state Medicaid program. Medicaid drug rebates are based on pricing data that the manufacturer must report on a monthly and quarterly basis to CMS. For the MDRP, this data includes the average manufacturer price (AMP) for each drug and, in the case of an innovator product, the best price (BP). If a manufacturer becomes aware that its MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, the manufacturer must resubmit the corrected data for up to three years after the data originally was due. In addition, there is increased focus by the Office of Inspector General within the U.S. Department of Health and Human Services on the methodologies used by manufacturers to calculate AMP, and BP, to assess manufacturer compliance with MDRP reporting requirements. If a manufacturer fails to provide information timely or is found to have knowingly submitted false information to the government, the manufacturer may be subject to civil monetary penalties and other sanctions, including termination from the MDRP, which would result in payment not being available for its covered outpatient drugs under Medicaid or, if applicable, Medicare Part B. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against a manufacturer under the Federal False Claims Act and other laws and regulations.

Federal law requires that a manufacturer that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program (the 340B program) in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by the Health Resources and Services Administration (HRSA) and requires a participating manufacturer to charge statutorily defined covered entities no more than the 340B "ceiling price" for its covered outpatient drugs used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive

health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Manufacturers must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. In addition, legislation may be introduced that, if passed, would further expand the 340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. Under the VA/FSS program, the manufacturer must report the Non-Federal Average Manufacturer Price (Non-FAMP) for its covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). The manufacturer must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If a manufacturer fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations are complex, vary among products and programs, and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. The terms, scope and complexity of these government pricing programs change frequently, as do interpretations of applicable requirements for pricing and rebate calculations. Responding to current and future changes may increase our costs and the complexity of compliance will be time consuming. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. Price recalculations under the MDRP also may affect the ceiling price at which we may be required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. In the event that CMS were to terminate a manufacturer's Medicaid rebate agreement, no federal payments would be available under Medicaid or Medicare for its covered outpatient drugs. We cannot assure you that submissions we make will not be found to be incomplete or incorrect.

If ZORYVE or any of our product candidates that are approved for marketing are found to have been improperly promoted for off-label uses by us, 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 consistent with the product's approved labeling.

Any regulatory approval that the FDA or a foreign regulatory authority grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective. For example, the FDA-approved label for ZORYVE cream 0.3% is limited to the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older, the label for ZORYVE cream 0.15% is limited to the topical treatment of atopic dermatitis in patients 6 years of age and older, and the label for ZORYVE foam 0.3% is limited to the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older, and we are not permitted to promote these products for any other uses, unless and until such uses are approved.

In addition, although we believe ZORYVE and 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 ZORYVE or our product candidates, if approved. If we are found to have promoted ZORYVE or any of our product candidates, if approved, 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 or in a manner inconsistent with approved labeling, 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 or promotion inconsistent with the label, 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 ZORYVE or 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 and patients may also misuse ZORYVE or 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 ZORYVE or 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

Raising additional funds by issuing securities may cause dilution to existing stockholders, 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.

If our available cash and marketable securities balances, amounts available under the Loan Agreement and anticipated future cash flows from operations are insufficient to satisfy our liquidity requirements, we may need to fund our operations through the sale of our equity securities, accessing or incurring additional debt, entering into licensing or collaboration agreements with partners, grants, or other sources of financing. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' 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 stockholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, our current Loan Agreement prohibits us from incurring certain additional indebtedness without the consent of our lender and restricts our ability to pay dividends.

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

In January 2024, we amended and restated our sales agreement, or Sales Agreement, with Cowen and Company, LLC, or Cowen, to reset the shares available for sale, from time to time, through our at-the-market equity offering program to such number of shares as would generate aggregate gross sales proceeds of up to $100.0 million. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, certain holders of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. In addition, we have an employment inducement incentive plan providing for an aggregate of 2.8 million shares of common stock to be issued pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, RSU awards, and other stock-based awards. We plan to register all of the shares under the employment inducement incentive plan. Once we register the shares described in the paragraph above, such shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

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

Our U.S. federal net operating loss (NOL) carryforwards generated in tax years beginning before January 1, 2018, may only be carried forward for 20 years under applicable U.S. tax law. Under current law, our federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change U.S. tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited.

As a result, our NOL carryforwards generated in tax years beginning before January 1, 2018 may expire prior to being used, and the deductibility of our NOL carryforwards generated in tax years beginning after December 31, 2017 will be subject to a percentage limitation, in taxable years beginning after December 31, 2020. In addition, we believe the Company has had ownership changes in the past and may have additional ownership changes in the future. These ownership changes could limit our ability to use all our NOL carryforwards, credit carryforwards, or other tax attributes. Similar provisions of state law also may apply to limit the use of our state net operating loss carryforwards or other tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, in June 2024, California enacted Senate Bill 167 (SB 167), which, with certain exceptions, suspends the ability to use California net operating losses to offset California income and limits the ability to use California business tax credits to offset California taxes, for taxable years beginning after 2023 and before 2027. While SB 167 did not have a material impact to the Company in 2024, it is possible that it may in future years.

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

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

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

discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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

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

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

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

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

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

General Risk Factors

Macroeconomic factors, including unfavorable or uncertain global and regional economic, political and health conditions, could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by global or regional economic, political and health conditions. For example, various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty), political uncertainty (such as during transitional periods for new administrations and changes to leadership positions within government or national offices, agencies, and divisions), conflicts, trade disputes between nations and the current and future conditions in the global financial markets. For example, if inflation or other factors were to significantly increase our business costs, we may be unable to manage such increased expenses or pass through price increases to purchasers of our approved products. In addition, the imposition of tariffs and other orders or restrictions impacting trade could adversely impact our business, including by increasing or otherwise impacting the costs and expenses we incur in connection with our operations and supply chain, and by potentially increasing the price of our products to purchasers of our approved products. The actual impacts of any tariffs and other orders or restrictions are subject to a number of factors including the effective date and duration of such tariffs, orders and restrictions, the amount, scope and nature of such inputs, any countermeasures that the target countries may take and any mitigating actions that may become available. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease, and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility and disrupt our business. Business disruptions could include, among others, disruptions to our commercial activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility and conduct of our clinical trials, as well as temporary closures of our facilities and the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and/or medications, which could have a negative impact on our commercial sales.

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

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

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

- limited daily trading volume resulting in the lack of a liquid market;
- the success of, and fluctuations in, the commercial sales of ZORYVE or any product candidates approved for commercialization in the future;
- the development status of our product candidates, including whether we discontinue development or if any of our product candidates receive regulatory approval;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- regulatory, legal or political developments in the United States and foreign countries;
- the results of our clinical trials and nonclinical studies;
- the clinical results of our competitors or potential competitors;
- the execution of our partnering and manufacturing arrangements;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our nonclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;

- variations in the level of expenses related to our commercialization activities for ZORYVE or any of our product candidates, if approved;
- 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;
- 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 report.

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

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

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

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

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

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

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

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

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

If a natural disaster, power outage or other event occurred, including an epidemic, pandemic or contagious disease outbreak 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.

Changes in tax laws or regulations could have a material adverse effect on our business and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. The Current Administration and Congress may propose various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flows, financial condition, or results of operations. Furthermore, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

In October 2021, the Organization for Economic Co-operation and Development (the OECD) announced the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting (the Framework), which agreed to a two-pillar solution to address tax challenges arising from digitalization of the economy. In December 2021, the OECD released Pillar Two Model Rules defining the global minimum tax rules, which contemplate a minimum tax rate of 15%. To date, various jurisdictions have enacted, or are in the process of enacting, legislation on these rules, and the OECD continues to release additional guidance. While it is uncertain whether the United States will enact legislation to adopt the minimum tax directive, certain countries in which we operate have adopted legislation to implement the minimum tax directive. Further, the OECD issued administrative guidance providing transition and safe harbor rules that could delay the impact of the minimum tax directive. While we continue to monitor the implementation of the Framework and its potential impact, we currently do not expect the Framework to have a material impact on the Company.

We could be subject to additional tax liabilities

We are subject to U.S. federal, state, local, and foreign income taxes in the United States, withholding taxes and transaction taxes in foreign jurisdictions. Significant judgement is required in evaluating our tax positions and our worldwide provision for taxes. During the ordinary course of business, there are many activities and transactions for which the ultimate tax determination is uncertain. We may be audited in various jurisdictions, and such jurisdictions may assess additional income, sales, and value-added or other taxes against us. Although we believe our tax estimates are reasonable, the final determination of any tax audits or litigation could be materially different from our historical tax provisions and accruals, which could have a material adverse effect on our operating results or cash flows in the period for which a determination is made.

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This does not imply that we meet any particular technical standards,

specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall risk management program, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for key service providers based on our assessment of their criticality to our operations and respective risk profile, suppliers, and vendors.
- Risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information, as well as risks of data leakage and unauthorized access to sensitive information.
- Ongoing review of the controls framework to support the security of emerging technologies, including artificial intelligence (AI) and generative AI (GenAI), ensuring alignment with evolving risks and regulatory expectations.

There can be no assurance that our and our third-party service providers', strategic partners', contractors', consultants', and collaborators' cybersecurity risk management program and processes, including policies, controls, or procedures, will be fully implemented, complied with, or effective in protecting our systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program.

The Audit Committee receives at least quarterly reports from our Chief Digital & Technology Officer and internal security staff on developments in our information technology infrastructure and cybersecurity program. This includes updates, as appropriate, on key information technology initiatives, new and existing cybersecurity risks, and how management is managing risks. In addition, the Chief Digital & Technology Officer updates the Audit Committee, where it deems appropriate, regarding any cybersecurity incidents it considers to be significant or potentially significant per our established severity and response framework.

The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also periodically receives briefings from management on our cyber risk management program and an annual report from management on our cybersecurity risks.

Our security technology team, led by the Head of Core Technology & Security (Head of CT&S), is responsible for managing and directing day-to-day assessment and management of materials risks from cybersecurity threats, including oversight of our cybersecurity tools, controls and strategies to protect organization assets, networks and data. The Head of CT&S reports to our Chief Digital and Technology Officer. The Head of CT&S has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. He is an ISACA certified security manager and has over 20 years of experience in information technology, with over 10 years specifically focused on cybersecurity risk management.

Our management takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal

security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our IT environment.

Item 2. PROPERTIES

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

Item 3. LEGAL PROCEEDINGS

Arcutis Biotherapeutics, Inc. filed a lawsuit against Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, Padagis) in the U.S. District Court for the District of Delaware on March 27, 2024, based on the submission to the FDA of an ANDA seeking approval to market and sell a generic version of Arcutis' ZORYVE® 0.3% cream for the treatment of plaque psoriasis. The Company asserts infringement of the following eleven patents, which are listed in the FDA's Orange Book for Arcutis' ZORYVE® 0.3% cream: 9,884,050; 9,907,788; 10,940,142; 11,129,818; 11,793,796;11,819,496; 11,992,480; 12,005,051; 12,005,052; 12,011,437; and 12,016,848 (collectively, Asserted Patents). Arcutis seeks a judgment that Padagis has infringed or will infringe one or more claims of each of the Asserted Patents and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Padagis's proposed generic product before expiration of each of the Asserted Patents found to infringe.

On July 19, 2024, Arcutis filed its first amended complaint that added the last five of the above listed patents to its infringement allegations. These patents were issued by the U.S. Patent and Trademark Office and listed in FDA's Orange Book for Arcutis's ZORYVE® 0.3% cream after the filing of the original complaint. On August 2, 2024, Padagis responded to the first amended complaint, denying infringement and asserting counterclaims seeking a declaratory judgement that the asserted patents are not infringed, invalid, and/or unenforceable. The court issued a scheduling order on June 10, 2024, which sets trial at the court's convenience, or around April 13-17, 2026. The automatic 30-month stay of FDA approval of Padagis's ANDA seeking approval for Arcutis's ZORYVE® 0.3% cream is set to expire on August 14, 2026.

Teva Pharmaceutical Industries Ltd. filed Oppositions with the European Patent Office against two of our European patents, European Patent Nos. EP 3634380 B1 and EP 3684334 B1, on September 20, 2024 and August 13, 2024, respectively. These patents relate to topical roflumilast compositions. Arcutis filed replies on January 23, 2025 and February 24, 2025, respectively. Hearings before the EPO's Opposition Division are not yet scheduled and the proceedings are ongoing.

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

Item 4. MINE SAFETY DISCLOSURES

None.

Part II

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

Market Information for Common Stock

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

Holders

As of February 19, 2025, there were approximately 61 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

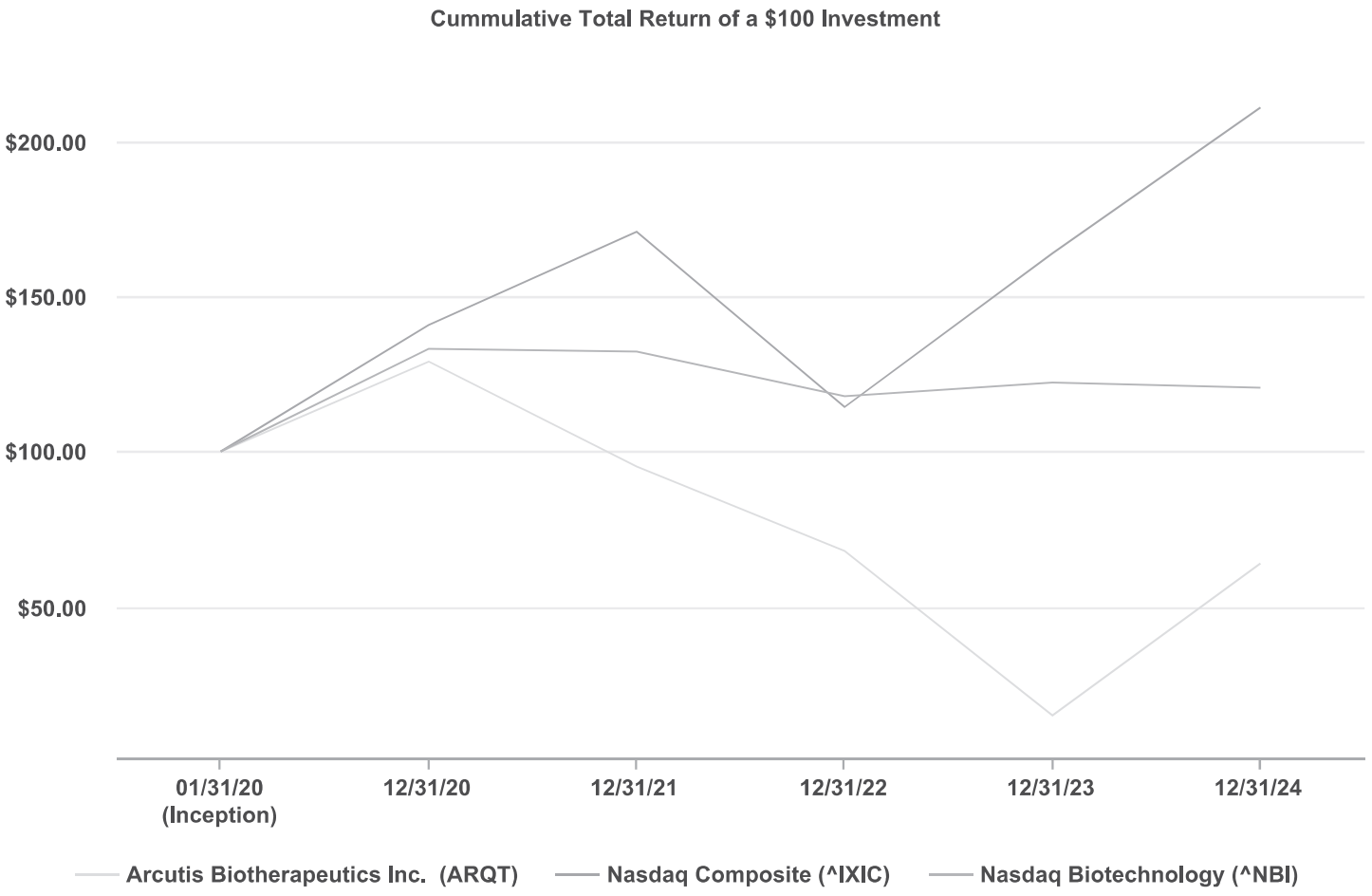
None.

Dividend Policy

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

Stock Performance Graph

The graph below shows a comparison, from January 31, 2020 (the date our common stock commenced trading on Nasdaq) through December 31, 2024, of the cumulative total return to stockholders of our common stock relative to the Nasdaq Composite Index (^IXIC) and the Nasdaq Biotechnology Index (^NBI). The graph assumes that $100 was invested in each of our common stock, the Nasdaq Composite and the Nasdaq Biotechnology at their respective closing prices on January 31, 2020 and assumes reinvestment of gross dividends. The stock price performance shown in the graph represents past performance and should not be considered an indication of future stock price performance. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



Cumulative Total Return Comparison

	1/31/2020 (Inception)	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
Arcutis Biotherapeutics, Inc.	$100.00	$129.04	$95.14	$67.89	$14.82	$63.90
Nasdaq Composite Index	$100.00	$140.84	$170.97	$114.38	$164.04	$211.03
Nasdaq Biotechnology Index	$100.00	$133.14	$132.30	$117.87	$122.27	$120.60

Item 6. RESERVED

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

The following discussion and analysis of our financial condition and results of operations should be read together with our "Selected Financial Data" and our audited financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. For a discussion of the year ended December 31, 2023 compared to the year ended December 31, 2022, refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans, objectives, expectations, projections and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors identified below and those set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results and the timing of selected events could differ materially from the forward-looking statements contained in the following discussion and analysis. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a commercial-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. Our current portfolio is comprised of highly differentiated topical and systemic treatments with significant potential to treat immune-mediated dermatological diseases and conditions. We believe we have built a leading platform for dermatologic product development and commercialization. Our strategy is to focus on validated biological targets, and to use our drug development platform and deep dermatology expertise to develop and commercialize differentiated products that have the potential to address the major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly advance our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

We launched our lead product, ZORYVE® (roflumilast) cream 0.3% (ZORYVE cream 0.3%) in August 2022 after obtaining our initial U.S. Food and Drug Administration (FDA) approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (e.g. groin or axillae), in individuals 12 years of age or older. ZORYVE cream 0.3% is a once-daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor. ZORYVE cream 0.3% is approved for once-daily treatment of mild, moderate, and severe plaque psoriasis with no limitations on location or duration of use. In October 2023, we received FDA approval for an expanded indication in plaque psoriasis down to 6 years of age. We are currently working with the FDA to potentially further expand this indication in plaque psoriasis down to 2 years of age following the generation of additional clinical data. In April 2023, we had our first commercial launch outside of the United States following Health Canada approval of ZORYVE cream 0.3% for the treatment of plaque psoriasis in individuals 12 years or age or older.

In December 2023, we received FDA approval for ZORYVE® (roflumilast) topical foam 0.3% (ZORYVE foam) for the treatment of seborrheic dermatitis in individuals aged 9 years and older, with no limitation on severity, location, or duration of use. ZORYVE foam is a once-daily steroid-free foam and, as a PDE4 inhibitor, is the first drug approved for the treatment of seborrheic dermatitis with a new mechanism of action in over two decades. ZORYVE foam became commercially available in the United States in late January 2024, and was approved by Health Canada in October 2024 and became commercially available in Canada in December 2024.

In addition to the approval of ZORYVE cream 0.3% for plaque psoriasis and ZORYVE foam for seborrheic dermatitis, we also received FDA approval for and commercially launched ZORYVE (roflumilast) cream 0.15% (ZORYVE cream 0.15%), (collectively, ZORYVE), in July 2024 for the treatment of mild to moderate atopic dermatitis in adults and pediatric patients 6 years of age and older, with no limitation on location, body surface area treated, concomitant use, or duration of use specified in the approved labelling. ZORYVE cream 0.15% is a once-daily, steroid-free cream that provides rapid disease clearance and significant reduction in itch and has been specifically developed to be a treatment option for long-term disease control. We have also completed a Phase 3 trial of ZORYVE cream 0.05% in pediatric patients 2 to 5 years of age with mild to moderate atopic dermatitis (INTEGUMENT-PED). Based on the positive results from the INTEGUMENT-PED study, and given our recent approval of ZORYVE cream 0.15% for the treatment of mild to moderate atopic dermatitis in individuals 6 years of age or older, we submitted a supplemental new drug application (sNDA) for topical ZORYVE cream 0.05% for children 2 to 5 years of age in December 2024. We conducted INTEGUMENT-OLE, an open label extension study of the long-term safety of ZORYVE cream 0.15% in subjects 6 years of age or older and ZORYVE cream 0.05% in

subjects between the ages 2 and 5 years, for which we reported positive results in September 2023 and August 2024, respectively.

Beyond seborrheic dermatitis, we are also developing ZORYVE foam for scalp and body psoriasis and have successfully completed our Phase 2b and pivotal Phase 3 clinical trials. We announced positive topline data in September 2022, with ZORYVE foam showing rapid disease clearance and significant reduction in itch. In the pivotal Phase 3 ARRECTOR study, at Week 8, 66% of individuals treated with ZORYVE foam achieved the co-primary efficacy endpoint of Scalp IGA Success, defined as a Scalp IGA score of “clear” or “almost clear” plus a 2-point improvement, and 46% of patients achieved the co-primary efficacy endpoint of Body IGA Success, defined as a Body IGA score of "clear" or "almost clear" plus a 2-point improvement. In addition, individuals treated with ZORYVE foam reported reductions in itch from baseline within 24 hours of first application. Based on the ARRECTOR results and a Phase 2b study, we submitted an sNDA to the FDA for a label expansion to include scalp and body psoriasis in adults and adolescents ages 12 and over, which was recently accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date in May 2025.

In July 2024, we entered into a co-promotion agreement with Kowa Pharmaceuticals, Inc. (Kowa) to leverage Kowa's primary care sales force to exclusively market and promote ZORYVE in the United States to primary care practitioners and pediatricians for all FDA-approved indications until at least July 2029. Under the terms of the agreement, Kowa will receive a commission from net sales attributed to Kowa. Promotion of ZORYVE in primary care and pediatrics under the Kowa agreement began in late September 2024.

In addition to ZORYVE, we are developing ARQ-255, a deep-penetrating topical formulation of ivarmacitinib, a potent and highly selective topical Janus kinase type 1 (JAK1) inhibitor, designed to preferentially deliver the drug deep into the hair follicle, the site of inflammation in alopecia areata, in order to potentially develop the first topical treatment for this disease. We completed enrollment in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata and expect data in the first half of 2025.

In September 2022, we acquired Ducentis BioTherapeutics LTD (Ducentis) and its lead asset, DS-234 (now ARQ-234), a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 Receptor (CD200R). Currently in the preclinical stage, we plan to develop ARQ-234 in atopic dermatitis, where we believe it could be a potentially highly complementary biologic treatment option to ZORYVE cream in that indication, if approved. ARQ-234 could potentially be used to treat other inflammatory conditions as well. We are working towards submitting an Investigational New Drug (IND) application during 2025.

We have incurred net losses in each year since inception, including net losses of $140.0 million, $262.1 million and $311.5 million for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, we had an accumulated deficit of $1,121.9 million and cash, cash equivalents, restricted cash and marketable securities of $228.6 million. As of December 31, 2024, we had $100.0 million outstanding under the Loan Agreement. We paid down $100.0 million of principal related to the Loan Agreement using available cash on October 8, 2024, with the right to re-draw that principal for a defined period.

We expect to continue to incur losses and significant expenses as we commercialize ZORYVE, and as we advance our product candidates and label extensions through clinical trials, regulatory submissions, and commercialization. We expect to incur significant and prioritized commercialization expenses related to the sales, marketing, manufacturing, and distribution of ZORYVE, while we focus our clinical development spend on ARQ-234, ARQ-255, and ZORYVE label extensions, if we obtain regulatory approval for them. If our available cash and marketable securities balances, amounts available under the Loan Agreement, and anticipated future cash flows from operations are insufficient to cover these expenses, we may need to fund our operations through equity or debt financings or other sources, such as future potential collaboration agreements. Adequate funding may not be available to us on acceptable terms, or at all. Any failure to obtain sufficient funds on acceptable terms if or when needed could have a material adverse effect on our business, results of operations, and financial condition. See “Liquidity, Capital Resources, and Requirements” below and Note 1 to the consolidated financial statements for additional information.

We rely on third parties to conduct our nonclinical studies and clinical trials and for manufacturing and supply of our product candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, many of whom are single source suppliers, for our nonclinical and clinical trial materials, as well as the commercial supply of our products.

Components of Our Results of Operations

Revenue

Product Revenue, Net

In August 2022, in conjunction with the launch of our first FDA approved product, ZORYVE cream 0.3%, we began to recognize revenue from product sales, net of rebates, chargebacks, discounts, and other adjustments. We also began recognizing revenue net of deductions for ZORYVE cream 0.3% in Canada in June 2023, ZORYVE foam in the United States in January 2024, ZORYVE cream 0.15% for atopic dermatitis in July 2024, and ZORYVE foam in Canada in December 2024. Additionally, if our development efforts for our other product candidates and ZORYVE label extensions are successful and result in regulatory approval, we may generate additional revenue in the future from product sales.

Other Revenue

Other revenue relates to our license agreements, primarily the Sato License Agreement and the Huadong License and Collaboration Agreement. See Note 7 to the consolidated financial statements for additional information.

Cost of Sales

Cost of sales includes direct and indirect costs related to the manufacturing and distribution of ZORYVE, including raw materials, third-party manufacturing costs, packaging services, and freight-in, as well as third-party royalties payable on our net product sales and amortization of intangible assets associated with ZORYVE.

Our cost of sales will reflect a lower average per unit cost of materials until inventory that was previously expensed is sold, which is expected to occur in the first half of 2025. As of December 31, 2024 and December 31, 2023, the value of this inventory, mostly at the raw materials stage, was approximately $5.5 million and $8.7 million, respectively.

Operating Expenses

Research and Development Expenses

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

We expect to continue to incur research and development expenses in the future as we develop our product candidates. In particular, we expect to incur research and development expenses for the phase 1 ARQ-255 study for alopecia areata, and early development of ARQ-234 for atopic dermatitis.

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

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing, or costs required to complete the remaining development of ZORYVE cream and ZORYVE foam, ARQ-255, and ARQ-234 or any other product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See “Risk Factors” for a discussion of the risks and uncertainties associated with the development of our product candidates.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, stock-based compensation, and travel, and costs related to sales and marketing of ZORYVE. Other selling, general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, insurance, and professional services fees for auditing, tax, and general legal services. The commission paid to Kowa under our co-promotion agreement is recorded as a selling expense. We expect our selling, general and administrative expenses to continue to increase in the future as we continue to commercialize ZORYVE and potentially other product candidates, and support our operations, including increased expenses related to legal, accounting, insurance, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors and officers liability insurance premiums, and investor relations activities.

Other Income, Net

Other income, net primarily consists of interest income earned on our cash, cash equivalents, and marketable securities, as well as changes in the fair value of the derivative related to our debt. See Note 9 to the consolidated financial statements for additional information.

Interest Expense

Interest expense is related to interest incurred on our long term debt.

Provision for Income Taxes

Provision for income taxes is related to the Huadong License and Collaboration Agreement. See Note 7 and Note 11 to the consolidated financial statements for additional information.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

Product revenue, net

We began recording U.S. product revenue in the third quarter of 2022 following the FDA approval and subsequent commercial launch of ZORYVE cream 0.3% in August 2022, and Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE cream 0.3% in June 2023. In the first quarter of 2024, we began recording U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE foam in January 2024. In the third quarter of 2024, we began recording U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE cream 0.15% in July 2024. In the fourth quarter of 2024, we began recording Canada product revenue following the Health Canada approval and subsequent commercial launch of ZORYVE foam in December 2024.

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Product revenue, net				
ZORYVE cream 0.3%	$ 85,082	$ 29,186	$ 55,896	192 %
ZORYVE foam	71,539	—	71,539	*
ZORYVE cream 0.15%	9,921	—	9,921	*
Total product revenue, net	$ 166,542	$ 29,186	$ 137,356	471 %

Product revenue, net, for ZORYVE cream 0.3% increased by $55.9 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily driven by higher end customer demand and improving gross-to-net discounts for ZORYVE cream 0.3% in the United States.

Product revenue, net, for ZORYVE foam increased by $71.5 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, driven by its commercial launch in January 2024.

Product revenue, net, for ZORYVE cream 0.15% increased by $9.9 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, driven by its commercial launch in July 2024.

Other revenue

Other revenue in the year ended December 31, 2024 is a result of license revenues received in connection with the Sato License Agreement of $25.0 million and the Huadong License and Collaboration Agreement of $5.0 million. Other revenue for the year ended December 31, 2023 primarily included licensed revenues received in connection with the Huadong License and Collaboration Agreement of $30.0 million. See Note 7 to the consolidated financial statements for additional information.

Cost of Sales

Cost of sales increased by $14.1 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase is related primarily to an increase in customer demand for ZORYVE cream 0.3% and launch of ZORYVE foam in 2024. Prior to the dates on which the initial regulatory approvals were received for each product, inventory manufacturing and raw materials costs were recorded as research and development expense. Therefore, cost of sales will reflect a lower average per unit cost until the related inventory is sold, which is expected to occur in the first half of 2025.

Research and Development Expenses

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 5,210	$ 35,607	$ (30,397)	(85)%
Topical JAK inhibitor program	2,945	3,334	(389)	(12)%
Other early stage programs	11,477	5,681	5,796	102 %
Indirect costs:				
Compensation and personnel-related	39,216	44,613	(5,397)	(12)%
Other	17,572	21,340	(3,768)	(18)%
Total research and development expense	$ 76,420	$ 110,575	$ (34,155)	(31)%

*Not applicable

Research and development expenses decreased by $34.2 million, or 31%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease was primarily due to the completion of Phase 3 studies of roflumilast cream in atopic dermatitis, coupled with decreases in compensation and personnel-related expenses, partially offset by manufacturing and preclinical costs incurred related to the development of early-stage programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $44.2 million, or 24%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to an increase in compensation and personnel related expenses of $28.9 million and an increase in sales and marketing expenses of $14.1 million. These increases were primarily due to our continued commercialization efforts for ZORYVE.

Other Income, Net

Other income, net increased by $4.4 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to the impact of higher interest rates on a higher marketable securities balance for the first three quarters of the year.

Interest Expense

Interest expense decreased by $2.5 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to the impact of lower interest rates and the partial prepayment of principal related to the Loan Agreement. See Note 9 to the consolidated financial statements for additional information.

Provision for Income Taxes

Income tax expense of $0.6 million for the year ended December 31, 2024 and $3.1 million for the year ended December 31, 2023 were due to income tax expense related to withholding taxes on payments received in connection with the Huadong License and Collaboration Agreement. See Note 7 and Note 11 to the consolidated financial statements for additional information.

Liquidity, Capital Resources and Requirements

Our primary sources of capital to date have been private placements of preferred stock, our IPO completed in January 2020, our follow-on financings in October 2020, February 2021, August 2022, October 2023, and March 2024, our Loan Agreement, our ATM program, and revenue from the sale of ZORYVE. We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop and commercialize our products and product candidates, including conducting nonclinical and clinical trials and providing selling, general and administrative support for these operations. As of December 31, 2024 and 2023, we had cash, cash equivalents, restricted cash, and marketable securities of $228.6 million and $272.8 million, respectively, and an accumulated deficit of $1,121.9 million and $981.9 million, respectively. We maintain cash

balances with financial institutions in excess of insured limits. As of December 31, 2024, we had $100.0 million outstanding under the Loan Agreement. We paid down $100.0 million of principal related to the Loan Agreement using available cash on October 8, 2024, with the right to re-draw that principal for a defined period. See Note 9 to the consolidated financial statements for additional information.

We believe that our existing capital resources will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of our financial statements.

If our capital resources are insufficient to satisfy our requirements, we may need to fund our operations through the sale of our equity securities, accessing or incurring additional debt, entering into licensing or collaboration agreements with partners, grants, or other sources of financing. There can be no assurance that sufficient funds will be available to us at all or on attractive terms when needed from these sources. If we are unable to obtain additional funding from these or other sources if or when needed it may be necessary to significantly reduce our current rate of spending through, among other things, reductions in staff and delaying, scaling back, or stopping certain research and development programs, nonclinical studies, clinical trials or other development activities, and commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. In addition, market conditions impacting financial institutions could impact our ability to access some or all of our cash, cash equivalents and marketable securities, and we may be unable to obtain alternative funding when and as needed on acceptable terms, if at all.

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

- the timing, receipt, and amount of sales of any current and future products;
- the scope, progress, results, and costs of researching and developing our product candidates or any future product candidates, and conducting nonclinical studies and clinical trials, in particular our planned or ongoing development activities and our formulation and nonclinical efforts;
- suspensions or delays in the enrollment or changes to the number of subjects we decide to enroll in our ongoing clinical trials;
- the number and scope of clinical programs we decide to pursue, and the number and characteristics of any product candidates we develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing ZORYVE or any future product candidates and any products we successfully commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities for ZORYVE or any future product candidates that are approved for sale, including marketing, sales and distribution costs, and any discounts or rebates to obtain access;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the costs related to milestone payments to AstraZeneca, Hengrui, or any future collaborator or licensing partner, upon the achievement of predetermined milestones;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio; and
- costs associated with any adverse market conditions or other macroeconomic factors.

Indebtedness

On December 22, 2021, we entered into a loan and security agreement (the Prior Loan Agreement) with SLR Investment Corp (SLR) and the lenders party thereto. The Prior Loan Agreement was amended and restated on January 10, 2023 (the AR Loan Agreement) to include Arcutis Canada, Inc., a corporation incorporated under the laws of the Province of Ontario, as a borrower and party. On November 1, 2023, we entered into an amendment to the AR Loan Agreement to, among others, (i) modify the financial covenant relating to minimum net product revenue, and (ii) include an additional minimum financing covenant. On August 9, 2024, we entered into a second amendment to the AR Loan Agreement (the AR Loan Agreement, as amended by the first and second amendments, the Loan Agreement) to, among others, (i) permit, during the period commencing on October 7, 2024 and ending on December 15, 2024, an optional partial prepayment of term loans outstanding, subject to a 1.0% prepayment penalty (the 2024 Partial Prepayment), (ii) add the tranche C-1 and tranche C-2 term loans, and (iii) facilitate certain other changes, including with respect to the applicable interest rate and maturity date in the event of a 2024 Partial Prepayment. The term loan facility is comprised of (i) a tranche A term loan of $75.0 million, (ii) a tranche B-1 term loan of $50.0 million, (iii) a tranche B-2 term loan of up to $75.0 million, (iv) a tranche C-1 term loan of up to $50.0 million, and (v) a tranche C-2 term loan of up to $50.0 million (collectively, the Term Loans). The tranche A term loan was funded in December 2021. With the approval of ZORYVE cream 0.3% on July 29, 2022, the tranche B term loans were funded in August 2022. As of December 31, 2024 and 2023, the aggregate principal amount outstanding under the Loan Agreement was $100.0 million and $200.0 million, respectively.

In October 2024, we made a 2024 Partial Prepayment of $100.0 million, which reduced the aggregate principal amount outstanding under the Loan Agreement to $100.0 million. In connection with the 2024 Partial Prepayment, we are obligated to pay a prepayment penalty of $1.0 million by June 30, 2026 and a final fee of $6.95 million, representing the final fee applicable to the amount of the 2024 Partial Prepayment, on January 1, 2027. As a result of such 2024 Partial Prepayment, subject us generating a minimum net product revenue for the trailing six (6) month period ending as of the month prior to the borrowing date equal to 80% of our projected net product revenue as set forth in its annual plan for the respective period, we will be able to draw down the tranche C-1 and tranche C-2 term loans. The tranche C-1 term loan availability will expire on March 31, 2026 and the tranche C-2 term loan availability will expire on June 30, 2026. In addition, as a result of the 2024 Partial Prepayment, (i) the maturity date of the Loan Agreement is August 1, 2029 (such date, the Maturity Date), (ii) the applicable per annum interest rate is equal to 5.95% plus the greater of (a) 2.50% per annum and (b) the one-month Secured Overnight Financing Rate (SOFR), (iii) we are no longer subject to certain cost and purchase price restrictions regarding acquisitions, and (iv) we may prepay principal amounts outstanding under the Term Loans in minimum increments of $25.0 million, subject to a prepayment premium of (a) 3.0% for any prepayment made prior to the first anniversary of the second amendment, (b) 2.0% for any prepayment made prior after the first anniversary of the second amendment and prior to the second anniversary of the second amendment, or (c) 1.0% for any prepayment made prior after the second anniversary of the second amendment and prior to the Maturity Date.

Principal amounts outstanding under the Term Loans will generally accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. Prior to the 2024 Partial Prepayment, the applicable rate was a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the one-month SOFR. As a result of such 2024 Partial Prepayment, the applicable interest rate will be a per annum interest rate equal to 5.95% plus the greater of (a) 2.50% and (b) the one-month SOFR. On December 31, 2024, the rate was 10.47%. The benchmark SOFR is subject to change in the event of certain events with respect to the benchmark rate. Interest payments are payable monthly following the funding of any Term Loan. Any principal amounts outstanding under the Term Loans, if not repaid or prepaid, are due and payable on August 1, 2029.

As security for the obligations under the Loan Agreement, we granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of our assets, including our intellectual property, subject to certain exceptions.

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

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions

on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. We also agreed to a financial covenant whereby we must generate a minimum net product revenue equal to 75% of our projected net product revenue as set forth in our annual plan for the respective period, tested on a trailing six-month basis as of the end of each month. Each annual plan shall be approved by our board of directors and SLR, in its capacity as collateral agent, in its reasonable discretion. Any failure by us to deliver such annual plan on or before December 15 of the prior year shall be an immediate event of default.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the Term Loans. Upon the occurrence and for the duration of an event of default, an additional default interest rate (the Default Rate) equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement.

In connection with the Loan Agreement, we are obligated to pay (i) a final fee equal to 6.95% of the aggregate original principal amount of the Term Loans outstanding as of the date of the second amendment, (x) with respect to any 2024 Partial Prepayment, upon the earliest to occur of (A) January 1, 2027, (B) the acceleration of all outstanding Term Loans and (C) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, and (y) with respect to the Term Loans outstanding as of the date of the second amendment (other than 2024 Partial Prepayment), upon the earliest to occur of (A) the Maturity Date, (B) the acceleration of all outstanding Term Loans and (C) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (ii) a 2.00% fee with respect to tranche C term loans, due and payable on the earliest to occur of (A) the Maturity Date, (B) the acceleration of all outstanding Term Loans and (C) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (iii) a 2.00% extension fee with respect to tranche C term loans which remain unfunded after December 31, 2025, which shall accrue during the period commencing January 1, 2026, and ending on the earliest to occur of (A) the expiration of the tranche C term loan availability, and (B) the date on which tranche C term loan is fully drawn, and (iv) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the original Prior Loan Agreement, we previously had entered into an Exit Fee Agreement, whereby we agreed to pay an exit fee in the amount of 3.0% of each Term Loan funded upon (i) any change of control transaction or (ii) a revenue milestone, calculated on a trailing six-month basis. Notwithstanding the prepayment or termination of the Term Loan, the exit fee will expire 10 years from the date of the Loan Agreement.

We were in compliance with all covenants under the Loan Agreement as of December 31, 2024.

Cash Flows

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (112,158)	$ (247,057)
Cash provided by (used in) investing activities	28,820	180,232
Cash provided by financing activities	66,202	101,323
Effect of exchange rate changes on cash	(235)	(50)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (17,371)	$ 34,448

Net Cash Used in Operating Activities

During the year ended December 31, 2024, net cash used in operating activities was $112.2 million, which consisted of a net loss of $140.0 million and a change in net operating assets and liabilities of $15.1 million, partially offset by net non-cash and other charges of $43.0 million. The change in net operating assets and liabilities was primarily due to an increase in accounts receivable of $47.3 million, offset by an increase in accounts payable and accrued liabilities of $34.3 million. The net non-cash and other charges were primarily related to stock-based compensation expense of $41.7 million.

During the year ended December 31, 2023, net cash used in operating activities was $247.1 million, which consisted of a net loss of $262.1 million and a change in net operating assets and liabilities of $23.5 million, partially offset by net non-cash and other charges of $38.6 million. The change in net operating assets and liabilities was primarily due to an increase in accounts receivable of $17.3 million, an increase in prepaid expenses and other current assets of $8.6 million, and an increase in inventories of $5.6 million, offset by an increase in accounts payable and accrued liabilities of $8.7 million. The net non-cash and other charges were primarily related to stock-based compensation expense of $38.8 million.

Net Cash Provided by (Used in) Investing Activities

During the year ended December 31, 2024, net cash provided by investing activities was $28.8 million, which was comprised primarily of the proceeds from the maturities of marketable securities of $288.8 million, partially offset by purchases of marketable securities of $254.8 million, as well as a milestone payment made to AstraZeneca of $5.0 million.

During the year ended December 31, 2023, net cash provided by investing activities was $180.2 million, which was comprised primarily of the proceeds from the maturities of marketable securities of $406.5 million, partially offset by purchases of marketable securities of $225.8 million.

Net Cash Provided by Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $66.2 million, which was comprised primarily of the net cash proceeds received from our February 2024 public stock offering of $161.7 million, offset by the 2024 Partial Prepayment of our long-term debt of $100.0 million.

During the year ended December 31, 2023, net cash provided by financing activities was $101.3 million, which was comprised primarily of the net cash proceeds received from our October 2023 public stock offering of $95.8 million and our December 2023 sale of stock under our ATM facility of $3.1 million.

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of December 31, 2024:

Facility Operating Lease

We lease a facility in Westlake Village, California under an operating lease that commenced in February 2019 and was amended in April 2020 in order to relocate to a new expanded space. The total commitment under the operating lease agreement is $3.8 million, including $1.0 million for each of the years 2025 and 2026, $1.1 million for the year 2027, and $0.7 million for the year 2028. See Note 8 to the consolidated financial statements for additional information.

Long-Term Debt Obligations

As of December 31, 2024, we had $100.0 million outstanding under our Loan Agreement. See Notes 1 and 9 to the consolidated financial statements for additional information. The undiscounted future payments of principal and interest under the Loan Agreement as of December 31, 2024 is $171.3 million, including $12.4 million for the year 2025, $13.6 million for the year 2026, $19.0 million for the year 2027, $12.2 million for the year 2028, and $114.1 million for the year 2029.

License Agreements & Acquisition

The terms of certain of our license agreements and our acquisition of Ducentis require us to pay potential future milestone payments based on product development and commercial success. The amount and timing of such obligations are unknown or uncertain. These potential obligations are further described in Note 7 to the consolidated financial statements.

Manufacturing Agreements

We have entered into manufacturing supply agreements for the commercial supply of ZORYVE, which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $7.5 million for 2025, and approximately $0.9 million per year for 2026 and 2027. This amount does not represent all of our anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

Indemnification

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

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Use of Estimates

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

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

Nonclinical and Clinical Accruals and Costs

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

accrued liabilities. We have not experienced any material differences between accrued costs as of December 31, 2024 and 2023 and actual costs incurred.

Revenues

Pursuant to Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* (ASC 606), we recognize revenue when a customer obtains control of promised goods or services. We record the amount of revenue that reflects the consideration that we expect to receive in exchange for those goods or services. We apply the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

We only apply the five-step model to contracts when it is probable that it will collect the consideration to which we are entitled in exchange for the goods or services that we transfer to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Product Revenue, Net

We sell our product to our Customers in the United States and Canada. Our Customers subsequently resell the products to pharmacies, health care providers, and patients. In accordance with ASC 606, we recognize net product revenues from sales when the Customers obtain control of our products, which typically occurs upon delivery to the Customer. Our payment terms are generally between 30 - 65 days.

Revenues from product sales are recorded at the net sales price, or “transaction price,” which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payer rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to trade receivables, net if payable to a Customer or accrued liabilities if payable to a third-party. Where appropriate, we utilize the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary from our estimates, we adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Distribution Service Fees: We engage with wholesalers to distribute our products to end customers. We pay the wholesalers a fee for services such as: data reporting, inventory management, chargeback administration, and service level commitment. We estimate the amount of distribution services fees to be paid to the Customers and adjust the transaction price with the amount of such estimate at the time of sale to the Customer.

Prompt Pay Discounts: We provide our Customers with a percentage discount on their invoice if the Customers pay within the agreed upon timeframe. We estimate the probability of Customers paying promptly based on the percentage of discount outlined in the agreement, and deduct the full amount of these discounts from its gross product revenues and accounts receivable at the time such revenues are recognized.

Product Returns: We provide Customers a return credit in the amount of the purchase price paid by Customers for all products returned in accordance with our returned goods policy. Once the product is returned, it is destroyed. We do not record a right-of-return asset.

In the early product launch period, we estimated a provision for sales returns based on industry data and adjusted the transaction price for such estimates at the time of sale to the Customer. As of the fourth quarter of 2024, we had collected history for our actual product returns, which we utilized to refine our returns rate and adjust our accrual. This analysis resulted in a $4.1 million reduction in our accrual and favorable true-up impact to product revenue in the fourth quarter of 2024 related to prior period estimates. We will continue to monitor our actual returns and if they vary from estimates, we may need to adjust accruals and reserve rates, which would affect revenue in the period of adjustment.

Chargeback: A chargeback is the difference between the manufacturer's invoice price to the wholesaler and the wholesaler's customer's contract price. The wholesaler tracks these sales and "charges back" the manufacturer for the difference between the negotiated prices paid between the wholesaler's customers and wholesaler's acquisition cost. We estimate the percentage of goods sold that are eligible for chargeback and adjust the transaction price for such discount at the time of sale to the Customer.

Co-payment Assistance: Patients who meet certain eligibility requirements may receive co-payment assistance. We recognize contra-revenue expense, and adjusts the transaction price for, co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Rebates and Discounts: We accrue rebates for contractually agreed-upon discounts with private payers and mandated discounts under government programs such as the Medicaid Drug Rebate Program in the United States. Our estimates for expected utilization of private payer rebates are based on data received from our customers. Our estimates for rebates under government programs are based on statutory discount rates and expected utilization as well as historical data we have accumulated since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual rebates vary from estimates, we may need to adjust accruals, which would affect revenue in the period of adjustment.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of December 31, 2024, we had cash and cash equivalents of $71.3 million, restricted cash of $0.6 million and marketable securities of $156.6 million, which consist of bank deposits, money market funds, commercial paper, government securities, and corporate debt securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that this exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

In addition, as of December 31, 2024, we had $100.0 million outstanding under our Loan Agreement. Amounts outstanding under our Loan Agreement bear interest at a floating rate equal a per annum interest rate equal to 5.95% plus the greater of (a) 2.50% and (b) the one-month Secured Overnight Financing Rate (SOFR). The benchmark SOFR is subject to change in the event of certain events with respect to the benchmark rate. As a result, we are exposed to risks related to our indebtedness from changes in interest rates. Based on the amount outstanding under our Loan Agreement as of December 31, 2024, for every 100 basis point increase in the interest rates, we would incur approximately $1.0 million of additional annual interest expense. We do not currently engage in hedging transactions to manage our exposure to interest rate risk, but higher interest expense would be offset in part by higher earnings on our cash and marketable securities. We may in the future use swaps, caps, collars, structured collars or other common derivative financial instruments to reduce interest rate risk. It is difficult to predict the effect that future hedging activities would have on our operating results.

We are exposed to foreign currency exchange risk as our Canadian subsidiary operates with the Canadian dollar as its functional currency. The majority of our transactions occur in U.S. dollars. The fluctuation in the value of the U.S. dollar against the Canadian dollar affects the reported amounts of expenses, assets and liabilities. If we expand our international operations our exposure to exchange rate fluctuations will increase. At December 31, 2024 we had cash balances denominated in Canadian dollars of $4.4 million. We currently do not hedge any foreign currency exposure. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have a material impact on our consolidated financial statements.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the our management, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of December 31, 2024 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such required information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Inherent Limitations over Controls and Procedures

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

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

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

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

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

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

Management Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Management conducted an assessment of the effectiveness of our internal control over financial reporting based our assessment on the criteria set forth in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2024. The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by an independent registered public accounting firm, as stated in their report included in Part IV Item 15, “Exhibits, Financial Statement Schedules” of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended December 31, 2024, which were identified in connection with management's evaluation required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control Over Financial Reporting

We have audited Arcutis Biotherapeutics, Inc.'s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Arcutis Biotherapeutics Inc.'s (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated February 25, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Los Angeles, California
February 25, 2025

Item 9B. OTHER INFORMATION

On December 13, 2024, Patrick Burnett, our Chief Medical Officer, entered into a Rule 10b5-1 trading plan, intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the potential sale of up to 177,732 shares of Common Stock held by Mr. Burnett between March 11, 2025 and February 27, 2026.

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

Not applicable.

Part III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We have adopted an insider trading policy and procedures governing the purchase, sale, and/or other dispositions of the our securities by directors, officers, employees and other covered persons that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and the listing requirements of the Nasdaq Global Select Market. This policy imposes regular blackout periods during which certain individuals may not transact in our securities and pre-clearance procedures for transactions by certain specified individuals, including, among others, the members of our board of directors and our executive officers. In addition, this policy prohibits certain transactions that we have determined are higher risk or for which there is a heightened appearance of potential improper or inappropriate conduct, including short sales of our securities, options trading in puts, calls or other derivative securities involving our equity securities, hedging transactions, and margin accounts and pledging of our securities. We regularly review our insider trading policy with our board of directors and management. A copy of our insider trading policy and procedures is filed as Exhibit 19 to this Annual Report on Form 10-K. Further, the company will not transact in any of its own securities unless in compliance with U.S. securities laws.

The remaining information required by this item is incorporated by reference to our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Part IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Financial Statement Schedules.

The following financial statements are included herein:

	Page
Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations and Comprehensive Loss	F-3
Consolidated Statements of Changes in Stockholders' Equity	F-4
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All other schedules are omitted because they are not applicable, not required, or because the required information is included in the consolidated financial statements or notes thereto.

(b) Exhibits. [YET TO BE UPDATED]

Exhibit Number	Description of Document	Incorporated by Reference Form	Date	Number	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation.	10-Q	5/12/20	3.1	
3.2	Restated Bylaws.	10-Q	5/12/20	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	1/21/20	4.1	
4.2†	Amended and Restated Investors' Rights Agreement, dated October 8, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	1/21/20	4.2	
4.3	Description of Arcutis Biotherapeutics' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	3/19/20	4.3	
4.4	Form of Pre-Funded Warrant	8-K	10/23/23	4.1	
10.1#	Form of Indemnity Agreement.	S-1	1/6/20	10.1	
10.2#	2017 Stock Incentive Plan and forms of award agreements.	S-1	1/6/20	10.2	
10.3#	2020 Stock Incentive Plan and forms of award agreements.	S-1/A	1/21/20	10.3	
10.4#	2020 Employee Stock Purchase Plan and forms of award agreements.	S-1/A	1/21/20	10.4	
10.5#	2022 Employment Inducement Incentive Plan and forms of award agreements.	10-K	2/22/22	10.5	
10.6#	Offer Letter, dated January 9, 2020, by and between the Registrant and Todd Franklin Watanabe.	S-1/A	1/21/20	10.5	
10.7#	Consulting Agreement, dated August 16, 2016, by and between Bhaskar Chaudhuri and the Registrant.	S-1	1/6/20	10.11	
10.8†^	License Agreement, dated July 23, 2018, by and between AstraZeneca AB and the Registrant.	S-1	1/6/20	10.12	
10.9†^	Exclusive Option and License Agreement, dated January 4, 2018, by and between Jiangsu Hengrui Medicine Co., Ltd. and the Registrant.	S-1	1/6/20	10.13	
10.10†^	Collaboration Agreement, dated June 28, 2019, by and between Hawkeye Therapeutics, Inc. and the Registrant.	S-1	1/6/20	10.14	
10.11#	Transition and Amendment Agreement, dated December 13, 2019 by and between Bhaskar Chaudhuri and the Registrant.	S-1	1/6/20	10.15	
10.12	Option Notice and Amendment No. 2 to Exclusive Option and License Agreement, dated December 5, 2019, by and between Jiangsu Hengrui Medicine Co., Ltd. and the Registrant.	S-1	1/6/20	10.16	
10.13#	Severance & Change in Control Agreement, by and between the Registrant and Todd Franklin Watanabe.	S-1/A	1/21/20	10.17	
10.14	Offer Letter, dated December 18, 2020, by and between the Registrant and Matthew R. Moore.	10-K	2/16/21	10.23	
10.15	Severance & Change in Control Agreement, by and between the Registrant and Matthew R. Moore.	10-K	2/16/21	10.24	
10.16†^	Supply Agreement, dated November 24, 2020, by and between Registrant and Interquim, S.A.	10-K	2/16/21	10.25	
10.17†^	Exclusive Distribution Agreement, dated February 8, 2021, by and between the Registrant and Cardinal Health 105, Inc.	10-Q	5/6/21	10.1	
10.18†^	Amendment No. 1, dated October 5, 2022, to the Supply Agreement, dated November 24, 2020, by and among the Registrant and Interquim, S.A.	10-Q	11/8/22	10.2	
10.19†	Supply and Manufacturing Agreement, dated September 15, 2021, between DPT Laboratories, Ltd. and the Registrant.	10-Q	11/4/21	10.1	

10.20	Offer Letter, dated December 13, 2021, by and between the Registrant and Mas Matsuda.	10-K	2/22/22	10.31	
10.21	Severance & Change in Control Agreement, by and between the Registrant and Mas Matsuda.	10-K	2/22/22	10.32	
10.22†	Share Purchase Agreement, dated September 7, 2022, by and among the Registrant, Ducentis Biotherapeutics LTD and the certain stockholders of Ducentis Biotherapeutics LTD.	10-Q	11/8/22	10.1	
10.23^	Amended and Restated Loan and Security Agreement, dated January 10, 2023, by and among the Registrant, SLR Investment Corp. and the lenders party thereto.	10-K	2/28/23	10.35	
10.24	First Amendment to Amended and Restated Loan and Security Agreement dated November 1, 2023, by and among the Registrant, SLR Investment Corp., and the lenders party thereto.	10-Q	11/3/23	10.2	
10.25	Non-Employee Director Compensation Program	10-K	2/28/23	10.36	
10.26	Form of Non-Employee Director RSU Deferral Election	10-K	2/28/23	10.37	
10.27	License Agreement, dated August 10, 2023, by and between the Registrant and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.	10-Q	11/3/23	10.1	
10.30	Employment Agreement, dated September 1, 2023, by and between John Smither and the Registrant	8-K	9/7/23	10.1	
10.31	Severance & Change in Control Agreement, dated September 6, 2023, by and between John Smither and the Registrant	8-K	9/7/23	10.2	
10.32	Employment Agreement, dated September 16, 2023, by and between Todd Edwards and the Registrant	8-K	9/27/23	10.1	
10.33	Severance and Change in Control Agreement, dated September 16, 2023, by and between Todd Edwards and the Registrant	8-K	9/27/23	10.2	
10.34	Amended and Restated Sales Agreement, dated January 31, 2024, by and between the Registrant and Cowen and Company, LLC	S-3	1/31/24	1.2	
10.35	Amendment to Employment Agreement, dated February 22, 2024, by and between the Registrant and Matthew R. Moore	10-K	2/27/24	10.35	
10.36	Offer Letter of Employment Agreement, dated April 5, 2024, by and between the Registrant and David Topper	8-K	4/10/24	10.1	
10.37	Severance and Change in Control Agreement, dated April 5, 2024, by and between the Registrant and David Topper	8-K	4/10/24	10.2	
10.38†	License Agreement, dated February 27, 2024, by and between the Registrant and Sato Pharmaceutical Co., Ltd.	10-Q	5/14/24	10.3	
10.39	First Amendment to the License Agreement, dated February 18, 2024, by and between the Registrant and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.	10-Q	5/14/24	10.4	
10.4^	Second Amendment to Amended and Restated Loan and Security Agreement, dated August 9, 2024, by and among the Registrant, Arcutis Canada, Inc., SLR Investment Corp., and the lenders party thereto.	10-Q	8/14/24	10.1	
19	Insider Trading Policy and Procedures	10-K	2/27/24	19	
23.1	Consent of Independent Registered Public Accounting Firm.				*

24.1	Power of Attorney (included in the signature page to this Annual Report on Form 10-K).				*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				**
97.1	Arcutis Biotherapeutics, Inc. Policy for Recovery of Erroneously Awarded Compensation	10-K	2/27/24	97.1	
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.				*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				*

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* Filed herewith.

** Furnished herewith.

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

^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

Indicates management contract or compensatory plan.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arcutis Biotherapeutics, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 25, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

Sales deductions

Description of the Matter

As of December 31, 2024, the Company recorded accrued sales deductions of $38.4 million. As described in Note 2 to the consolidated financial statements, revenues from product sales are recognized net of variable consideration for invoice discounts for prompt payment and distribution service fees, government and private payer rebates, chargebacks, discounts and fees, product returns and costs of co-pay assistance programs, which are collectively recorded at the time of sale.

Auditing the accrued liabilities related to private payer rebates required significant judgment. The accrued sales deductions related to private payer rebates are based on data received from its customers, current contractual arrangements, market events and trends, external historical data, and forecasted customer buying patterns and patient utilization. Auditing the Company's accounting for accrued sales deductions related to co-pay assistance programs requires a higher degree of judgment to evaluate the relevance and reliability of audit evidence. The accrued sales deductions related to co-pay assistance programs are estimated based on historical program payments and utilization.

How We Addressed the Matter in Our Audit

To test the adequacy of the Company's accrued sales deductions for private payer rebates and co-pay assistance we obtained management's calculations for the estimates and performed the following procedures, among others. For accrued private payer rebates, we tested management's estimation process by developing an independent expectation of the estimated accrual balance based upon actual historical payment data. We also tested terms and conditions for a sample of contracts to the executed agreement and tested a sample of payments made throughout the year. For accrued co-pay assistance programs, we assessed the company's assumptions of distributor inventory quantities by agreeing the quantities to third party reports. We also assessed the historical share and payment rate assumptions by testing a sample of the historical payments and program utilization.

/s/ Ernst & Young LLP

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

Los Angeles, California
February 25, 2025

ARCUTIS BIOTHERAPEUTICS, INC.

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,335	$ 88,398
Restricted cash	617	925
Marketable securities	156,620	183,463
Trade receivables, net	73,066	25,807
Inventory	14,526	13,134
Prepaid expenses and other current assets	19,656	18,704
Total current assets	335,820	330,431
Property and equipment, net	1,041	1,539
Intangible assets, net	9,479	6,438
Operating lease right-of-use asset	1,953	2,361
Other assets	596	596
Total assets	$ 348,889	$ 341,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,220	$ 11,992
Accrued liabilities	65,973	33,941
Operating lease liability	820	735
Total current liabilities	81,013	46,668
Operating lease liability, noncurrent	2,562	3,382
Long-term debt, net	107,203	201,799
Other long-term liabilities	570	849
Total liabilities	191,348	252,698
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized; 117,848,033 and 96,787,343 shares issued and outstanding at December 31, 2024 and 2023, respectively	12	9
Additional paid-in capital	1,279,479	1,070,558
Accumulated other comprehensive income (loss)	(7)	4
Accumulated deficit	(1,121,943)	(981,904)
Total stockholders' equity	157,541	88,667
Total liabilities and stockholders' equity	$ 348,889	$ 341,365

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

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Year Ended December 31,		
	2024	2023	2022
Revenues:			
Product revenue, net	$ 166,542	$ 29,186	$ 3,686
Other revenue	30,000	30,420	—
Total revenues	196,542	59,606	3,686
Operating expenses:			
Cost of sales	19,128	4,987	754
Research and development	76,420	110,575	182,435
Selling, general and administrative	229,391	185,145	122,124
Total operating expenses	324,939	300,707	305,313
Loss from operations	(128,397)	(241,101)	(301,627)
Other income (expense):			
Other income, net	16,173	11,786	5,821
Interest expense	(27,168)	(29,712)	(15,652)
Loss before income taxes	(139,392)	(259,027)	(311,458)
Provision for income taxes	647	3,113	—
Net loss	$ (140,039)	$ (262,140)	$ (311,458)
Other comprehensive income (loss):			
Unrealized income (loss) on marketable securities	219	1,186	(831)
Foreign currency translation adjustment	(230)	(96)	—
Total other comprehensive income (loss)	(11)	1,090	(831)
Comprehensive loss	$ (140,050)	$ (261,050)	$ (312,289)
Per share information:			
Net loss per share, basic and diluted	$ (1.16)	$ (3.78)	$ (5.66)
Weighted-average shares used in computing net loss per share, basic and diluted	120,957,633	69,305,487	55,032,265

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

ARCUTIS BIOTHERAPEUTICS, INC.

Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2021	50,255,614	$ 5	$ 706,233	$ (255)	$ (408,306)	$ 297,677
Issuance of shares of common stock for public offering, net of issuance costs of $634	882,353	—	14,366	—	—	14,366
Issuance of shares of common stock net of discount and issuance costs of $10,844	8,625,000	1	161,656	—	—	161,657
Issuance of shares of common stock related to the acquisition of Ducentis Biotherapeutics	610,258	—	12,468	—	—	12,468
Issuance of common stock upon the exercise of stock options	331,890	—	1,016	—	—	1,016
Issuance of common stock upon the vesting of restricted stock units	118,174	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	75,293	—	82	—	—	82
Shares issued pursuant to the ESPP	138,821	—	1,922	—	—	1,922
Stock-based compensation expense	—	—	32,682	—	—	32,682
Unrealized loss on marketable securities	—	—	—	(831)	—	(831)
Net loss	—	—	—	—	(311,458)	(311,458)
Balance—December 31, 2022	61,037,403	6	930,425	(1,086)	(719,764)	209,581
Issuance of shares of common stock for public offering, net of issuance costs of $6,546	33,425,000	3	95,762	—	—	95,765
Issuance of common stock from ATM offering, net of issuance costs of $116	1,250,000	—	3,136	—	—	3,136
Issuance of common stock upon the exercise of stock options	348,169	—	1,247	—	—	1,247
Issuance of common stock upon the vesting of restricted stock units	440,262	—	—	—	—	—
Lapse of repurchasing rights related to common stock issued pursuant to early exercises	14,847	—	—	—	—	—
Shares issued pursuant to the ESPP	271,662	—	1,175	—	—	1,175
Stock-based compensation expense	—	—	38,813	—	—	38,813
Unrealized gain on marketable securities	—	—	—	1,186	—	1,186
Foreign currency translation adjustment	—	—	—	(96)	—	(96)
Net loss	—	—	—	—	(262,140)	(262,140)
Balance—December 31, 2023	96,787,343	9	1,070,558	4	(981,904)	88,667
Issuance of common stock and pre-funded warrants, net of issuance costs of $10,820	18,157,895	3	161,679	—	—	161,682
Issuance of common stock upon the exercise of stock options	649,109	—	2,807	—	—	2,807
Issuance of common stock upon the vesting of restricted stock units	1,719,962	—	—	—	—	—
Shares issued pursuant to the ESPP	533,724	—	1,713	—	—	1,713
Stock-based compensation expense	—	—	42,722	—	—	42,722
Unrealized gain on marketable securities	—	—	—	219	—	219
Foreign currency translation adjustment	—	—	—	(230)	—	(230)
Net loss	—	—	—	—	(140,039)	(140,039)
Balance—December 31, 2024	117,848,033	$ 12	$ 1,279,479	$ (7)	$(1,121,943)	$ 157,541

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

ARCUTIS BIOTHERAPEUTICS, INC.

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2024	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (140,039)	$ (262,140)	$ (311,458)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	640	771	622
Non-cash lease expense	408	360	319
Amortization of intangible assets	1,959	750	312
Acquired in-process research and development	—	—	29,630
Net amortization/accretion on marketable securities	(6,901)	(6,989)	(2,253)
Non-cash interest expense	5,404	4,030	2,606
Stock-based compensation	41,730	38,813	32,682
Change in fair value of embedded derivative instrument	(279)	849	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(47,259)	(17,349)	(8,458)
Inventories	(400)	(5,620)	(7,514)
Prepaid expenses and other current assets	(948)	(8,621)	3,472
Accounts payable	2,229	3,152	1,565
Accrued liabilities	32,033	5,594	1,193
Operating lease liabilities	(735)	(657)	(433)
Net cash used in operating activities	(112,158)	(247,057)	(257,715)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of marketable securities	(254,820)	(225,840)	(415,389)
Proceeds from maturities of marketable securities	288,783	406,500	351,473
Purchases of property and equipment	(143)	(428)	(333)
Acquisition of in-process research and development	—	—	(15,450)
Milestone payment for intangible asset	(5,000)	—	(7,500)
Net cash provided by (used in) investing activities	28,820	180,232	(87,199)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock, net of issuance costs	161,682	—	161,592
Repayment of long-term debt	(100,000)	—	—
Proceeds from issuance of common stock upon exercise of stock options	2,807	1,247	1,016
Proceeds from issuance of common stock for ESPP	1,713	1,175	1,922
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	—	95,765	—
Proceeds from long-term debt	—	—	125,000
Proceeds from issuance of shares under ATM, net of issuance costs	—	3,136	14,455
Payment of debt issuance costs	—	—	(2,187)
Net cash provided by financing activities	66,202	101,323	301,798
Effect of exchange rate changes on cash	(235)	(50)	—
Net increase (decrease) in cash, cash equivalents and restricted cash	(17,371)	34,448	(43,116)
Cash, cash equivalents and restricted cash at beginning of period	89,323	54,875	97,991
Cash, cash equivalents and restricted cash at end of period	$ 71,952	$ 89,323	$ 54,875
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:			
Interest expense paid in cash	$ 22,209	$ 25,445	$ 12,636
Acquired in-process research and development in exchange for the issuance of common stock	$ —	$ —	$ 12,468

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

1. Organization and Description of Business

Arcutis Biotherapeutics, Inc., or the Company, is a commercial-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. The Company's strategy is to focus on validated biological targets and to use its drug development platform and deep dermatology expertise to develop differentiated products that have the potential to address the major shortcomings of existing therapies in its targeted indications.

The Company received U.S. Food and Drug Administration (FDA) approval of its first product, ZORYVE® (roflumilast) cream 0.3% (ZORYVE cream 0.3%), on July 29, 2022, for the treatment of plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older (subsequently approved down to 6 years old), and began U.S. commercialization in August 2022. The Company also received Health Canada approval of ZORYVE cream in plaque psoriasis on April 28, 2023 and began Canadian commercialization in June 2023. The Company received FDA approval of ZORYVE® (roflumilast) topical foam 0.3% (ZORYVE foam), on December 15, 2023, for the treatment of seborrheic dermatitis in individuals 9 years of age and older, and began U.S. commercialization in late January 2024. The Company received FDA approval of ZORYVE® (roflumilast) cream 0.15%, (ZORYVE cream 0.15%) on July 9, 2024, for the treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older, and began U.S. commercialization in late July 2024. The Company received Health Canada approval of ZORYVE foam in October 2024.

Initial Public Offering and Follow-On Financings

On February 4, 2020, the Company closed an initial public offering (IPO) issuing and selling shares of common stock receiving aggregate net proceeds of approximately $167.2 million. The Company completed subsequent public sales of its common stock in October 2020, February 2021 and August 2022, receiving aggregate net proceeds of $93.4 million, $207.5 million, and $161.6 million, respectively.

In addition to the sale of common stock, the offering completed in October 2023 consisted of prefunded warrants to purchase 7,500,000 shares of the Company's common stock at $2.4999 per underlying share of common stock. The exercise price of the warrants is $0.0001 per underlying share of common stock. The prefunded warrants are exercisable at any time on or after their original issuance, and were not exercised as of December 31, 2024.

On February 28, 2024, the Company completed an offering relating to the sale of 15,789,474 shares of the Company's common stock at $9.50 per share. The Company also granted the underwriters an option to purchase up to an additional 2,368,421 shares at $9.50 per share, which the underwriters exercised in full on February 29, 2024. The aggregate net proceeds to the Company was $161.7 million after deducting underwriting discounts, commissions, and estimated offering expenses payable by the Company.

At-the-Market (ATM) Offerings

On May 6, 2021, the Company entered into a sales agreement (Sales Agreement) with Cowen and Company, LLC (Cowen), under which the Company may from time to time issue and sell shares of its common stock through ATM offerings for an aggregate offering price of up to $100.0 million. Cowen will act as the Company's sales agent for the ATM program and is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold under the Sales Agreement. In March, 2022, the Company sold 882,353 shares under the ATM for $17.00 per share and received $14.5 million in net proceeds. In December 2023, the Company sold 1,250,000 shares under the ATM for $2.60 per share and received $3.1 million in net proceeds.

In January 2024, the Company amended and restated its Sales Agreement with Cowen to reset the ATM program to provide for the offer and sale of shares of common stock having an aggregate gross offering price of up to $100.0 million. All other terms of the amended and restated Sales Agreement are substantially the same as the original Sales Agreement. The Company has not yet issued or sold any common stock under the amended and restated Sales Agreement.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $1,121.9 million and $981.9 million as of December 31, 2024 and 2023, respectively. Management expects to continue to incur operating losses. The Company had cash, cash equivalents, restricted cash, and marketable securities of $228.6 million and $272.8 million as of December 31, 2024 and 2023, respectively. The Company has $100.0 million outstanding under the Loan Agreement as of December 31, 2024. See Note 9.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP). The consolidated financial statements include the Company's wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates such estimates and assumptions for continued reasonableness. In particular, management makes estimates with respect to revenue recognition, accruals for research and development activities, stock-based compensation expense, and income taxes. Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation. Actual results could differ from those estimates. See below for change in prior period estimates related to revenue recognition which was recorded in the fourth quarter of 2024.

Cash and Cash Equivalents

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

Restricted Cash

As of December 31, 2024 and 2023, the Company held $0.6 million and $0.9 million, respectively, of restricted cash as collateral for a letter of credit related to the Company's amended office space lease. See Note 8.

Marketable Securities

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

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

Trade Receivables, net

The Company's trade accounts receivable consists of amounts due primarily from pharmaceutical wholesalers and specialty pharmacy providers in the United States and Canada (collectively, its Customers) related to sales of ZORYVE and have standard payment terms. For certain Customers, the trade accounts receivable for the Customer is net of distribution service fees, prompt pay discounts, and other adjustments. The Company monitors the financial performance and creditworthiness of its Customers so that it can properly assess and respond to changes in their credit profile. The Company will reserve against trade accounts receivable for estimated credit losses that may arise and any amounts determined to be uncollectible will be written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated losses was not material as of December 31, 2024 and 2023.

Inventory

The Company values its inventories at the lower-of-cost or net realizable value. The Company determines the cost of its inventories, which includes costs related to products held for sale in the ordinary course of business, products in process of production for such sale, and items to be currently consumed in the production of goods to be available for sale, on a first-in, first-out (FIFO) basis. Due to the nature of the Company's supply chain process, inventory that is owned by the Company is physically stored at third-party warehouses, logistics providers, and contract manufacturers. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such charges are recorded as a component of cost of sales in the consolidated statements of operations. The Company capitalizes inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. Products that may be used in clinical development programs are excluded from inventory and their costs are charged to research and development expense in the consolidated statement of operations as incurred, as long as they do not have an alternative use. Prior to the initial dates of regulatory approval, costs related to the production of inventory were recorded as research and development expense on the Company's consolidated statements of operations in the period incurred.

Intangible Assets, net

The Company paid a milestone payment of $7.5 million to AstraZeneca in the third quarter of 2022 related to the FDA approval and launch of ZORYVE cream 0.3%. This milestone payment was capitalized as an intangible asset and will be amortized to cost of sales over its useful life of 10 years from the date of first commercial sale, as this is the minimum amount of time that the related License Agreement will be in effect. The Company paid an additional milestone payment of $5.0 million related to the achievement of $100.0 million worldwide net sales in the third quarter of 2024. This milestone payment was recorded as a cumulative catch-up adjustment to the carrying value of the intangible asset. Amortization expense was $2.0 million, $0.8 million, and $0.3 million for the years ended December 31, 2024, 2023, and 2022, respectively. See Note 7.

Estimated future amortization expense for the intangible assets subsequent to December 31, 2024 is as follows (in thousands):

	Amounts
2025	$ 1,250
2026	1,250
2027	1,250
2028	1,250
2029	1,250
Thereafter	3,229
Total amortization	$ 9,479

The Company evaluates its long-lived assets, including intangibles, for impairment whenever events or changes in circumstance indicate that the carrying value of an asset might not be fully recoverable. To do so, the Company compares the carrying value of the intangible asset to the undiscounted net cash flows over its remaining useful life, and if not recoverable, will estimate the fair value of the asset. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Valuation of Other Investments

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by either the financial institutions holding its cash or by its customers owing trade receivables to the extent recorded on the consolidated balance sheets. To manage accounts receivable credit risk, the Company continuously evaluates the creditworthiness of its customers and the need for an allowance for potential credit losses.

Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 4, include cash equivalents, accounts receivable, accounts payable, accrued liabilities, and long-term debt. The carrying amount of cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their fair values due to their short maturities. As the long-term debt is subject to variable interest rates that are based on market rates which regularly reset, the Company believes that the carrying value of the long-term debt approximates its fair value.

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

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

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

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

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets which range from two to five years. Leasehold improvements are depreciated on a straight-line basis over the shorter of their estimated useful lives or lease terms. Maintenance and repairs are expensed as incurred. The Company reviews the carrying values of its property and equipment for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There were no impairments recognized during the years ended December 31, 2024, 2023 and 2022.

Leases

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

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

Accrued and Prepaid Nonclinical and Clinical Costs

The Company records accrued liabilities for estimated costs and prepaid costs for research and development activities conducted by third-party service providers, which include the conduct of nonclinical studies, clinical trials, and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities and prepaid costs balances in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities.

Revenues

Pursuant to Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* (ASC 606), the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Product Revenue, Net

The Company sells its product to its Customers in the United States and Canada. The Company's Customers subsequently resell the products to pharmacies, health care providers, and patients. In accordance with ASC 606, the Company recognizes net product revenue from sales when the Customers obtain control of the Company's products, which typically occurs upon delivery to the Customer. The Company's payment terms are generally between 30 - 65 days.

Revenue from product sales are recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payer rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to trade receivables, net if payable to a Customer or accrued liabilities if payable to a third-party. Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known. See below for change in prior period estimates related to revenue recognition which was recorded in the fourth quarter of 2024.

Distribution Service Fees: The Company engages with wholesalers and specialty pharmacies to distribute its products to end customers. The Company pays the wholesalers and certain specialty pharmacies a fee for

services such as: data reporting, inventory management, chargeback administration, and service level commitment. The Company estimates the amount of distribution services fees to be paid to the Customers and adjusts the transaction price with the amount of such estimate at the time of sale to the Customer.

Prompt Pay Discounts: The Company provides some of its Customers with a percentage discount on their invoice if the Customers pay within the agreed upon timeframe. The Company estimates the probability of Customers paying promptly based on the percentage of discount outlined in the purchase agreement between the two parties, and deducts the full amount of these discounts from its gross product revenue and accounts receivable at the time such revenue is recognized.

Product Returns: The Company provides Customers a return credit in the amount of the purchase price paid by Customers for all products returned in accordance with the Company's returned goods policy. Once the product is returned, it is destroyed. The Company does not record a right-of-return asset.

In the early product launch period, the Company estimated its provision for sales returns based on industry data and adjusted the transaction price for such estimates at the time of sale to the Customer. As of the fourth quarter of 2024, the Company had collected history for its actual product returns, which it utilized to refine its estimated returns rate and adjust its accrual. This analysis resulted in a $4.1 million reduction in its accrual and favorable true-up impact to product revenue in the fourth quarter of 2024 related to adjusting prior period estimates. The Company will continue to monitor its actual returns and if they vary from estimates, the Company may need to adjust accruals and reserve rates, which would affect revenue in the period of adjustment.

Chargeback: A chargeback is the difference between the manufacturer's invoice price to the wholesaler and the wholesaler's customer's contract price. The wholesaler tracks these sales and "charges back" the manufacturer for the difference between the negotiated prices paid between the wholesaler's customers and wholesaler's acquisition cost. The Company estimates the percentage of goods sold that are eligible for chargeback and adjusts the transaction price for such discount at the time of sale to the Customer.

Co-payment Assistance: Patients who meet certain eligibility requirements may receive co-payment assistance. The Company records contra-revenue for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Rebates and Discounts: The Company accrues rebates for contractually agreed-upon discounts with private payers and mandated discounts under government programs such as the Medicaid Drug Rebate Program in the United States. The Company's estimates for expected utilization of private payer rebates are based on data received from its customers. The Company's estimates for rebates under government programs are based on statutory discount rates and expected utilization as well as historical data it has accumulated since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual rebates vary from estimates, the Company may need to adjust accruals, which would affect revenue in the period of adjustment.

Other Revenue

Other revenue is related to the Huadong License and Collaboration Agreement and Sato License Agreement. See Note 7. The Company evaluated the agreements with Huadong and Sato and determined that they are within the scope of ASC 606. The Company applied the five-step model as required by ASC 606 to determine revenue recognition.

The nonrefundable upfront payments received in connection with the transfer of the license and related know-how to Huadong in September 2023 and to Sato in March 2024 were determined to be distinct performance obligations, and therefore were recognized in Other revenue.

The Company evaluated whether the development and regulatory milestones are considered probable of being reached and determined that their achievement is highly dependent on factors outside of the Company's control. Therefore, these payments are subject to significant revenue reversal and are therefore not included in the transaction price. At the end of each reporting period, the Company will re-evaluate the probability of achievement of each milestone and, if necessary, adjust its estimate of the overall transaction price and accordingly recognize

the related revenue once the probability of significant reversal of revenue is low. Any such adjustments are recorded on a cumulative catch-up basis, and would be reported in Other revenue in the period of adjustment.

The sales milestones and royalties will be recognized in Other revenue when the related sales occur.

Cost of Sales

Cost of sales includes direct and indirect costs related to the manufacturing and distribution of ZORYVE, including raw materials, third-party manufacturing costs, packaging services, freight-in, third-party royalties payable on the Company's net product revenue, and amortization of certain intangible assets associated with ZORYVE. Cost of sales may also include period costs related to certain inventory warehouse and distribution operations and inventory adjustment charges. The Company began capitalizing inventory costs upon related FDA approval dates for each product. As a result, manufacturing and other inventory costs incurred prior to FDA approval were expensed and, therefore, are not included in cost of sales.

Research and Development

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

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, stock-based compensation, and travel, and costs related to sales and marketing of ZORYVE. Other selling, general and administrative expenses include legal costs of pursuing patent protection of the Company's intellectual property, insurance, and professional services fees for auditing, tax, and general legal services. Advertising costs are expensed as incurred and were $6.9 million, $11.2 million, $1.5 million for the years ended December 31, 2024, 2023, and 2022, respectively.

Pre-funded Warrants

Pursuant to the Company's offering relating to the sale of securities completed in October 2023, the Company issued pre-funded warrants to purchase 7,500,000 shares of the Company's common stock at $2.4999 per underlying share of common stock. The warrants had an exercise price of $0.0001 per underlying share of common stock, were fully exercisable upon issuance, and have no expiration date. The shares underlying the pre-funded warrants, the exercise of which requires nominal consideration for the delivery of the shares of common stock, are included in weighted-average shares used in computing net loss per share as of December 31, 2024 and 2023. See Note 1.

Stock-Based Compensation

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

concludes that it is probable that the awards with a performance condition will be achieved on an accelerated attribution method. The Company accounts for forfeitures as they occur.

Income Taxes

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

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

Foreign Currency Translation

The Company translates the assets and liabilities of its foreign subsidiaries where the local currencies have been determined to be the functional currencies into U.S. dollars using current exchange rates. Adjustments for foreign currency translation adjustments are recognized in other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss. The earnings or loss of these subsidiaries are translated in U.S. dollars using average exchange rates in effect during each reporting period.

Net Loss Per Share

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

Co-promotion Agreement

In July 2024, the Company entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. (Kowa) to leverage Kowa's primary care sales force to exclusively market and promote ZORYVE to primary care practitioners and pediatricians for all FDA-approved indications until July 2029. The Company recognizes all revenue and Kowa receives a commission for the net sales attributed to Kowa, which is reflected in selling, general and administrative expense. For the year ended December 31, 2024, revenue from sales attributed to Kowa were immaterial and related commissions were immaterial.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07*, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. The Company adopted the guidance in the fiscal year beginning January 1, 2024. There was no impact on the Company's reportable segments identified and additional required disclosures have been included in Note 13.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires qualitative and quantitative updates to the rate reconciliation and income taxes paid disclosures, among others, in order to enhance the transparency of income tax disclosures, including consistent categories and greater disaggregation of information in the rate reconciliation and disaggregation by jurisdiction of income taxes paid. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments should be applied prospectively; however, retrospective application is also permitted. The Company is currently evaluating the impact of adopting ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03.

3. Revenues

Revenues are recognized under guidance within ASC 606, *Revenue from Contracts with Customers*. The following table presents the Company's disaggregated revenue for the periods presented (in thousands):

	Year Ended December 31,		
	2024	2023	2022
ZORYVE cream 0.3%	$ 85,082	$ 29,186	$ 3,686
ZORYVE foam	71,539	—	—
ZORYVE cream 0.15%	9,921	—	—
Total product revenue, net	166,542	29,186	3,686
Other revenue	30,000	30,420	—
Total revenues	$ 196,542	$ 59,606	$ 3,686

Other revenue relates primarily to the Sato and Huadong licensing agreements. See Note 7.

Major customers are defined as customers that individually accounted for greater than 10% of the Company's revenue. The following table presents each major customer that accounted for more than 10% of its gross product sales.

	Year Ended December 31,		
% of gross product sales	2024	2023	2022
Customer A	16 %	13 %	*
Customer B	14 %	21 %	45 %
Customer C	13 %	*	*
Customer D	12 %	13 %	16 %
Customer E	*	22 %	22 %
Customer F	*	*	15 %
Total gross product sales from major customers	55 %	69 %	98 %

* Represents less than 10% of respective balance

As of December 31, 2024, amounts due from five of these customers each exceeded 10% of gross trade receivables and accounted for 69% of net trade receivables on a combined basis. As of December 31, 2023, amounts due from four of these customers each exceeded 10% of gross trade receivables and accounted for 68% of net trade receivables on a combined basis.

4. Fair Value Measurements

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

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 71,335	$ —	$ —	$ 71,335
Certificates of deposit	—	5,042	—	5,042
Corporate debt securities	—	83,955	—	83,955
U.S. Treasury securities	67,623	—	—	67,623
Total assets	$ 138,958	$ 88,997	$ —	$ 227,955

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 73,544	$ —	$ —	$ 73,544
Commercial paper	—	11,806	—	11,806
Corporate debt securities	—	59,954	—	59,954
U.S. Treasury securities	126,557	—	—	126,557
Total assets	$ 200,101	$ 71,760	$ —	$ 271,861

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

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

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

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

	December 31, 2024			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 71,335	$ —	$ —	$ 71,335
Total cash and cash equivalents	$ 71,335	$ —	$ —	$ 71,335
Marketable securities:				
Certificates of deposit	$ 5,042	—	—	$ 5,042
Corporate debt securities	83,855	100	—	83,955
U.S. Treasury securities	67,404	219	—	67,623
Total marketable securities	$ 156,301	$ 319	$ —	$ 156,620

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

	December 31, 2023			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 73,544	$ —	$ —	$ 73,544
Corporate debt securities	14,851	3	—	14,854
Total cash and cash equivalents	$ 88,395	$ 3	$ —	$ 88,398
Marketable securities:				
Commercial paper	$ 11,817	$ 1	$ (12)	$ 11,806
Corporate debt securities	45,056	45	(1)	45,100
U.S. Treasury securities	126,492	82	(17)	126,557
Total marketable securities	$ 183,365	$ 128	$ (30)	$ 183,463

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

As of December 31, 2024, all securities have a maturity of 18 months or less and there were no individual securities that were in a significant unrealized loss position. The Company generally holds its marketable securities until maturity and does not intend to sell, and is not required to sell, the investments that are in an unrealized loss position before the recovery of their amortized cost basis.

The following table summarizes the change in the fair value of the embedded derivative instrument for the year ended December 31, 2024 and 2023 (in thousands). There was no activity for the year ended December 31, 2022.

	December 31,	
	2024	2023
Beginning balance	$ 849	$ —
Loss (gain) from changes in fair value	(279)	849
Ending balance	$ 570	$ 849

The fair value of the Company's embedded derivative instrument is based on significant inputs not observed in the market, and thus represents a Level 3 measurement. Refer to Note 9 for further discussion on the embedded derivative instrument.

5. Balance Sheet Components

Inventories

The components of inventory are summarized as follows (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 4,300	$ 9,951
Work in progress	584	486
Finished goods	9,642	2,697
Total inventories	$ 14,526	$ 13,134

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2024	2023
Prepaid co-pay assistance program and rebates	$ 7,369	$ 8,608
Prepaid clinical trial costs	3,244	1,024
Prepaid insurance	844	864
Other prepaid expenses and current assets	8,199	8,208
Total prepaid expenses and other current assets	$ 19,656	$ 18,704

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2024	2023
Accrued sales deductions	$ 38,430	$ 11,578
Accrued compensation	20,747	14,872
Clinical trial accruals	—	4,192
Accrued expenses and other current liabilities	6,796	3,299
Total accrued liabilities	$ 65,973	$ 33,941

6. Property and Equipment, net

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

	December 31,	
	2024	2023
Computer hardware	$ 1,272	$ 1,130
Furniture and fixtures	661	661
Software	104	104
Leasehold improvements	1,568	1,568
Property and equipment, gross	3,605	3,463
Less accumulated depreciation	(2,564)	(1,924)
Property and equipment, net	$ 1,041	$ 1,539

Depreciation expense was $0.6 million, $0.8 million, and $0.6 million for the years ended December 31, 2024, 2023, and 2022 respectively. Leasehold improvements are depreciated over the term of the lease, which is the shorter of the improvements' expected useful lives and the lease term. All other fixed asset depreciation is recorded using the straight-line method over the estimated useful lives of the assets (two to five years).

7. License Agreements & Acquisition

Sato License Agreement

On February 27, 2024, the Company entered into a License Agreement with Sato Pharmaceutical Co., Ltd. (Sato). Pursuant to the terms of the License Agreement, the Company grants to Sato an exclusive, sublicensable (under certain circumstances) license under certain patent rights and know-how controlled by the Company for Sato to develop, conduct medical affairs activities for, manufacture, commercialize, and otherwise exploit roflumilast formulations (the Licensed Products) for all therapeutic uses for certain dermatological indications in humans (the Field) in Japan (the Territory).

The License Agreement sets forth each party's respective obligations with respect to the development, medical affairs activities, manufacture and supply, and commercialization of the Licensed Products. Pursuant to the terms of the License Agreement, Sato will, at its expense, develop, obtain regulatory approval for, commercialize, and conduct medical affairs activities related to the Licensed Products in the Field in Japan, subject to certain of the Company's approval and oversight rights.

Pursuant to the terms of the License Agreement, the Company received an upfront payment of $25.0 million and will potentially receive additional payments (i) up to an aggregate amount of $10.0 million upon the achievement of certain regulatory milestones and (ii) up to an aggregate amount of $30.0 million upon the achievement of certain sales milestones. In addition, on a Licensed Product-by-Licensed Product basis, commencing from the first commercial sale of such Licensed Product in Japan until the latest of (i) the expiration of the last valid claim in the intellectual property rights licensed by the Company to Sato under the License Agreement covering such Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Licensed Product in Japan, or (iii) ten years after the first commercial sale of such Licensed Product in Japan, the Company will receive low double-digit to mid-teen double-digit percentage royalties on Sato's, its affiliates' and sublicensees' total annual net sales of all Licensed Products, subject to certain royalty reductions.

The term of the License Agreement continues until, on a Licensed Product-by-Licensed Product basis, the expiration of the Royalty Term. The License Agreement may be terminated by either party in its entirety if the other party commits a material breach, subject to a cure period, or if the other party becomes insolvent. Sato may terminate the License Agreement at-will in its entirety upon 90 days' written notice. Unless unenforceable under applicable law, the Company may terminate the License Agreement in its entirety if Sato, its affiliate or sublicensee contests or assists a third party in contesting the scope, validity or enforceability of any patent or patent application licensed by the Company to Sato. The Company may also terminate the License Agreement if Sato or any director, officers, employee, agent, affiliate, sublicensee, or subcontractor is charged by a governmental authority for a violation of any anti-corruption, anti-money laundering, sanctions or export or import control laws or regulations, or,

subject to the terms of the License Agreement, if Sato, its affiliates and sublicensees do not conduct any material development or commercialization activities of a Licensed Product in Japan for a certain period of time.

Other revenue under the Sato agreement was $25.0 million for the year ended December 31, 2024.

Huadong License and Collaboration Agreement

In August 2023, the Company entered into a license and collaboration agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd (Huadong), a wholly owned subsidiary of Huadong Medicine Co., Ltd. Pursuant to the terms of the agreement, the Company granted to Huadong an exclusive, sublicensable (under certain circumstances) license under certain patent rights and know-how controlled by the Company for Huadong to develop, conduct medical affairs activities for, manufacture, commercialize, and otherwise exploit both cream and foam topical roflumilast for all therapeutic uses for certain dermatological indications (Huadong Licensed Products) in Greater China (mainland China, Hong Kong, Macau, and Taiwan) and Southeast Asia (Indonesia, Singapore, The Philippines, Thailand, Myanmar, Brunei, Cambodia, Laos, Malaysia, and Vietnam) (Huadong Territories).

Huadong will, at its expense, develop, obtain regulatory approval for, commercialize, and conduct medical affairs activities for the Huadong Licensed Products, subject to certain of the Company's approval and oversight rights. The Company will retain exclusive rights for the development, manufacture and commercialization of topical roflumilast outside the Huadong Territories.

As consideration for the rights granted under the Huadong Agreement, Huadong paid the Company a non-refundable upfront fee pursuant to the terms of the agreement, upon closing in September 2023. The Company received a net payment of $27.0 million, which consisted of a $30.0 million upfront payment less the applicable tax withholding obligation in China of $3.0 million. In addition, the Company received a net payment of $2.7 million in March 2024, which consisted of $3.0 million related to the achievement of a development and regulatory milestone less the applicable tax withholding of $0.3 million. The Company received a net payment of $1.8 million in December 2024 which consisted of $2.0 million related to the achievement of a development and regulatory milestone less the applicable tax withholding of $0.2 million. The Company may also potentially receive additional payments: (i) up to an aggregate amount of $19.0 million upon the achievement of certain development and regulatory milestones, (ii) up to an aggregate amount of $40.3 million upon the achievement of certain sales milestones, and (iii) low double-digit to high-teen double-digit tiered percentage royalties on net sales of the Huadong Licensed Products.

The term of the Huadong Agreement continues on a Licensed Product-by-Licensed Product and country or region-by-country or region basis, until the expiration of the Royalty Term, which is: (i) the date of expiration of the last valid patent claim related to the Huadong Licensed Products, (ii) ten years after the first commercial sale of a the Huadong Licensed Product and (iii) the expiration of any regulatory exclusivity as to a Huadong Licensed Product. The License Agreement may be terminated by both parties under certain circumstances.

Other revenue and related income tax expense related to the Huadong agreement was $5.0 million and $0.5 million, respectively, for the year ended December 31, 2024. Other revenue and related tax income expense related to the Huadong agreement was $30.0 million and $3.0 million, respectively, for the year ended December 31, 2023.

AstraZeneca License Agreement

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

The Company paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of Series B convertible preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement, which were both recorded in research and development expense. The Company subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of ZORYVE cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product, which was recorded in research and development expense. In the third quarter of 2022, the Company paid $7.5 million to AstraZeneca as a result of the approval of ZORYVE cream 0.3%, which was recorded as an intangible asset. In the third quarter of 2024, the Company paid $5.0 million to AstraZeneca upon achievement of $100.0 million in worldwide net sales, which was recorded as a cumulative catch-up adjustment to the carrying value of the intangible asset. The Company is amortizing the intangible asset to cost of sales over its useful life of 10 years from the date of first commercial sale as this is the minimum amount of time that the related License Agreement will be in effect. Amortization expense was $2.0 million, $0.8 million and $0.3 million for the years ended December 31, 2024, 2023, and 2022, respectively.

The Company has agreed to make additional cash payments to AstraZeneca of up to an aggregate of $5.0 million upon the achievement of specified regulatory approval milestones with respect to the AZ-Licensed Products, and a payment of $10.0 million when the Company achieves $250.0 million in worldwide sales. With respect to any AZ-Licensed Products the Company commercializes under the AstraZeneca License Agreement, it will pay AstraZeneca a low to high single-digit percentage royalty rate on the Company's, its affiliates' and its sublicensees' net sales of such AZ-Licensed Products, subject to specified reductions, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. As a result of the commercialization of ZORYVE cream in August 2022, the Company began accruing royalties payable to AstraZeneca, which are recorded in cost of sales and accrued liabilities. Royalty expense during the year ended December 31, 2024 was $5.0 million. Royalty expense during the years ended December 31, 2023 and 2022 was not material.

Hengrui Exclusive Option and License Agreement

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

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

In June 2022, the Company entered into a side letter agreement with Hengrui and one of its subsidiaries to extend certain rights and obligations under the Hengrui License Agreement to the subsidiary under specified circumstances, including a change of control of such subsidiary.

There were no payments made or due in connection with Hengrui for the years ended December 31, 2024, 2023 and 2022.

Ducentis Biotherapeutics LTD Acquisition

On September 7, 2022, the Company entered into a Share Purchase Agreement with Ducentis Biotherapeutics LTD (Ducentis), pursuant to which the Company acquired (the Acquisition) all of the outstanding equity interests in Ducentis for (i) 610,258 shares of the Company common stock valued at approximately $12.5 million and $15.9 million in cash, inclusive of liabilities acquired, and (ii) contingent payments of up to an aggregate of $400 million, which may become payable upon the achievement of certain development, regulatory, and commercial milestones. In addition, if applicable, the Company will make payments amounting to a mid-single-digit percentage of any annual net sales of Ducentis' products exceeding $1.5 billion. The Company accounted for this purchase as an in-process research and development (IPR&D) asset acquisition as it has no alternative future use and recorded a charge to research and development expense in the amount of $29.6 million on the acquisition date. The contingent payments incurred in connection with the Acquisition will be recorded when it is probable that they will occur and they can be reasonably estimated, at which point the Company will determine whether the payment should be expensed or capitalized depending on whether the IPR&D has achieved market acceptance.

There were no payments made or due in connection with the Ducentis acquisition for the years ended December 31, 2024, 2023 and 2022.

Under the terms of the Share Purchase Agreement, the Company will develop and seek FDA approval of a therapeutic product containing Ducentis' DS-234 product candidate, now ARQ-234, for an atopic dermatitis indication, and if FDA approval of ARQ-234 is obtained by the Company, to launch it in the United States.

8. Commitments and Contingencies

Operating Lease

The Company leases a facility in Westlake Village, California which terminates in July 2028, with a renewal option for a term of five years. The Company also has a one-time option to cancel the lease in July 2026.

The lease also requires the Company to have an available letter of credit which has a related restricted cash account of $0.9 million and $0.6 million as of December 31, 2023 and 2024, respectively.

The minimum annual rental payments of the Company's operating lease liability as of December 31, 2024 are as follows (in thousands):

	Amounts
2025	$ 1,024
2026	1,054
2027	1,087
2028	653
Total minimum lease payments	3,818
Less: Amounts representing interest	(436)
Present value of future minimum lease payments	$ 3,382
Current portion operating lease liability	820
Operating lease liability, noncurrent	2,562
Total operating lease liability	$ 3,382

Straight-line rent expense recognized for operating leases was $745,000, $737,000, and $716,000 for the years ended December 31, 2024, 2023, and 2022, respectively.

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

	December 31,		
	2024	2023	2022
Cash flows from operating activities			
Cash paid for amounts included in the measurement of lease liabilities	$ 994	$ 965	$ 781

The following summarizes additional information related to the operating lease:

	December 31, 2024
Weighted-average remaining lease term (in years)	3.6
Weighted-average discount rate	7.0 %

Manufacturing Agreements

The Company has entered into manufacturing supply agreements for the commercial supply of ZORYVE which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $7.5 million for 2025 and $0.9 million per year for 2026 and 2027. This amount does not represent all of the Company's anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

Indemnification

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

9. Long-term debt

On December 22, 2021, the Company entered into a loan and security agreement (the Prior Loan Agreement) with SLR Investment Corp. (SLR) and the lenders party thereto. The Prior Loan Agreement was amended and restated on January 10, 2023 (the AR Loan Agreement) to include Arcutis Canada, Inc. as a borrower and party. On November 1, 2023, the Company entered into an amendment to the AR Loan Agreement to, among others, (i) modify the financial covenant relating to minimum net product revenue, and (ii) include an additional minimum financing covenant. On August 9, 2024, the Company entered into a second amendment to the AR Loan Agreement (the AR Loan Agreement, as amended by the first and second amendments, the Loan Agreement), which it determined to be a modification, to, among others, (i) permit, during the period commencing on October 7, 2024 and ending on December 15, 2024, an optional partial prepayment of term loans outstanding, subject to a 1.0% prepayment penalty (the 2024 Partial Prepayment), (ii) add the tranche C-1 and tranche C-2 term loans, and (iii) facilitate certain other changes, including with respect to the applicable interest rate and maturity date in the event of a 2024 Partial Prepayment. As security for the obligations under the Loan Agreement, the Company granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of the Company's assets, including its intellectual property, subject to certain exceptions. The term loan facility is comprised of (i) a tranche A term loan of $75.0 million, (ii) a tranche B-1 term loan of $50.0 million, (iii) a tranche B-2 term loan of up to $75.0 million, (iv) a tranche C-1 term loan of up to $50.0 million, and (v) a tranche C-2 term loan of up to $50.0 million (collectively, the Term Loans). The tranche A term loan was funded on December 22, 2021. With the approval of ZORYVE cream 0.3% on July 29, 2022, the tranche B term loans were funded on August 2, 2022. As of December 31, 2024 and 2023, the aggregate principal amount outstanding under the Loan Agreement was $100.0 million and $200.0 million, respectively.

On October 8, 2024, the Company made a 2024 Partial Prepayment of $100.0 million, which reduced the aggregate principal amount outstanding under the Loan Agreement to $100.0 million. In connection with the 2024 Partial Prepayment, the Company is obligated to pay a prepayment penalty of $1.0 million by June 30, 2026 and a final fee of $6.95 million, representing the final fee applicable to the amount of the 2024 Partial Prepayment, on January 1, 2027.

As a result of such 2024 Partial Prepayment, subject to the Company generating a minimum net product revenue for the trailing six (6) month period ending as of the month prior to the borrowing date equal to 80% of the Company’s projected net product revenue as set forth in its annual plan for the respective period, the Company will be able to draw down the tranche C-1 and tranche C-2 term loans. The tranche C-1 term loan availability will expire on March 31, 2026 and the tranche C-2 term loan availability will expire on June 30, 2026. In addition, as a result of the 2024 Partial Prepayment, (i) the maturity date of the Loan Agreement is August 1, 2029, (ii) the applicable per annum interest rate is equal to 5.95% plus the greater of (a) 2.50% per annum and (b) the one-month Secured Overnight Financing Rate (SOFR), (iii) the Company is no longer subject to certain cost and purchase price restrictions regarding acquisitions, and (iv) the Company may prepay principal amounts outstanding under the Term Loans in minimum increments of $25.0 million, subject to a prepayment premium of (a) 3.0% for any prepayment made prior to the first anniversary of the second amendment, (b) 2.0% for any prepayment made prior after the first anniversary of the second amendment and prior to the second anniversary of the second amendment, or (c) 1.0% for any prepayment made prior after the second anniversary of the second amendment and prior to the maturity date.

Principal amounts outstanding under the Term Loans will accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. Prior to the 2024 Partial Prepayment, the applicable rate was a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the one-month SOFR. As a result of such 2024 Partial Prepayment, the applicable interest rate will be a per annum interest rate equal to 5.95% plus the greater of (a) 2.50% and (b) the one-month SOFR. On December 31, 2024, the rate was 10.47%. The benchmark SOFR is subject to change in the event of certain events with respect to the benchmark rate. Interest payments are payable monthly following the funding of any Term Loan.

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

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on the Company's ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. The Company also agreed to a financial covenant whereby the Company must generate a minimum net product revenue equal to 75% of its projected net product revenue as set forth in the Company's annual plan for the respective period, tested on a trailing six-month basis, as of the end of each month. Each annual plan shall be approved by the Company's board of directors and SLR, in its capacity as collateral agent, in its reasonable discretion. Any failure by the Company to deliver such annual plan on or before December 15 of the prior year shall be an immediate event of default. The Company was in compliance with all covenants under the Loan Agreement as of December 31, 2024.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the Term Loans. Under the Loan Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Loan Agreement, the Company breaches any of the covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, the lenders determine that a material adverse change has occurred, or the Company or the Company's assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement. The prepayment upon default and other potential additional interest provisions under the Loan Agreement were determined to be a compound embedded derivative instrument to be bifurcated from the loan and accounted for as a separate liability for accounting purposes under the guidance in ASC 815, Derivatives and Hedging. At the inception of the Loan Agreement, the fair value of the embedded derivative was determined to be immaterial. The embedded derivative instrument is remeasured at fair value each reporting period with any future changes in fair value reported in Other income, net in the consolidated statement of operations and comprehensive loss. During the year ended December 31, 2024 and 2023, the Company recognized a $0.3 million gain and $0.8 million loss, respectively, in Other income, net. No gain or loss was recognized during the year ended December 31, 2022. The fair value of the embedded derivative instrument as of December 31, 2024 and 2023 was a liability of $0.6 million and $0.8 million, respectively, and is included in Other-long term liabilities in the accompanying consolidated balance sheets. See Note 4.

In connection with the Loan Agreement, the Company is obligated to pay (i) a final fee equal to 6.95% of the aggregate original principal amount of the Term Loans outstanding as of the date of the second amendment (x) with respect to any 2024 Partial Prepayment, upon the earliest to occur of (a) January 1, 2027, (b) the acceleration of all outstanding Term Loans and (c) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, and (y) with respect to the Term Loans outstanding as of the date of the second amendment (other than the 2024 Partial Prepayment), upon the earliest to occur of (a) the maturity date, (b) the acceleration of all outstanding Term Loans and (c) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (ii) a 2.00% fee with respect to tranche C term loans, due and payable on the earliest to occur of (a) the maturity date, (b) the acceleration of all outstanding Term Loans and (c) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (iii) a 2.00% extension fee with respect to tranche C term loans which remain unfunded after December 31, 2025, which shall accrue during the period commencing January 1, 2026, and ending on the earliest to occur of (a) the expiration of the tranche C term loan availability, and (b) the date on which tranche C term loan is fully drawn, and (iv) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the original Prior Loan Agreement, the Company previously had entered into an Exit Fee Agreement, whereby the Company agreed to pay an exit fee in the amount of 3.0% of

each Term Loan funded upon (i) any change of control transaction or (ii) a revenue milestone, calculated on a trailing six-month basis. Notwithstanding the prepayment or termination of the Term Loan, the exit fee will expire 10 years from the date of the Loan Agreement.

The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan. Interest expense is calculated using the effective interest method, and is inclusive of non-cash amortization of debt issuance costs. The final maturity payment of $13.9 million is recognized over the life of the term loan through interest expense. At December 31, 2024 and 2023, the effective interest rate was 11.57% and 14.81%, respectively. Interest expense relating to the term loan was $27.2 million, $29.7 million and $15.7 million, respectively, for the year ended December 31, 2024, 2023 and 2022.

The following summarizes additional information related to the Company's long-term debt (in thousands):

	December 31,	
	2024	2023
Long-term debt, gross	$ 100,000	$ 200,000
Accrued final fee	7,324	4,876
Accrued prepayment penalty	1,000	—
Unamortized debt issuance costs	(1,121)	(3,077)
Long-term debt, net	$ 107,203	$ 201,799

Upon the contractual maturity of the Company's long term debt, a payment of principal and final fees of $107.0 million is due on August 1, 2029.

10. Stock-Based Compensation

In January 2020, the Company's board of directors approved the 2020 Equity Incentive Plan (2020 Plan), which became effective January 30, 2020 in connection with the IPO. The 2020 Plan serves as the successor incentive award plan to the Company's 2017 Equity Incentive Plan (2017 Plan) and initially reserved 2,134,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, and other stock-based awards, plus 1,550,150 shares of common stock that were reserved for issuance pursuant to future awards under the 2017 Plan at the time the 2020 Plan became effective, plus shares represented by awards outstanding under the 2017 Plan that are forfeited or lapsed unexercised and which following the effective date of the 2020 Plan are not issued under the 2017 Plan. In addition, the 2020 Plan reserve will increase on January 1 of each year beginning in 2021 through 2030, by an amount equal to the lesser of (a) four percent of the shares of stock outstanding (on an as converted basis) on the day immediately prior to the date of increase and (b) such smaller number of shares of stock as determined by the Company's board of directors; provided, however, that no more than 11,000,000 shares of stock may be issued upon the exercise of incentive stock options. Accordingly, on January 1, 2025, 2024 and 2023, the 2020 Plan reserve increased by 4,713,921, 3,871,494, and 2,442,090 shares, respectively. As of December 31, 2024, the Company had 3,126,304 shares available for future grant under the 2020 Plan.

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

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

In December 2021, the Company's board of directors approved the 2022 Employment Inducement Incentive Plan (2022 Plan). The 2022 Plan initially reserved 1,250,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation

rights, restricted stock awards, RSU awards, and other stock-based awards. In November 2022, the 2022 Plan reserve was increased by 1,500,000. As of December 31, 2024, the Company had 401,134 shares available for future grant under the 2022 Plan.

Stock Option Exchange Program

On January 16, 2024, the Company commenced an offer to certain eligible employees and consultants to exchange certain outstanding eligible options to purchase shares of the Company's common stock for a lesser number of restricted stock unit (RSU) awards pursuant to an option exchange program (the Option Exchange). The Option Exchange expired on February 12, 2024. Pursuant to the Option Exchange, eligible option holders elected to exchange, and the Company accepted for cancellation, eligible options to purchase an aggregate of 5,059,129 shares of the Company's common stock, representing approximately 98% of the total shares of common stock underlying the eligible options. On February 13, 2024, immediately following the expiration of the Option Exchange, the Company granted 2,129,594 shares of Replacement RSU Awards, pursuant to the terms of the Option Exchange. The Replacement RSU Awards will vest based on continued service with the Company over a period of either 1, 2 or 3 years, depending on the grant date of the exchanged options.

The exchange of stock options was treated as a modification for accounting purposes, which requires an incremental expense of $8.6 million to be recognized for the Replacement RSU Awards over their new service periods (1 - 3 years). In addition, any unamortized expense remaining on the exchanged options as of the modification will be recognized over their original remaining service period.

Stock Option Activity

The following summarizes option activity:

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($ in thousands)
Balance—December 31, 2023	7,919,699	$ 18.52	7.35	$ 1,435
Granted	3,765,916	5.27		
Exercised	(649,109)	4.33		
Forfeited[(1)]	(5,384,872)	22.37		
Expired	(308,725)	24.44		
Balance—December 31, 2024	5,342,909	$ 6.69	8.01	$ 43,120
Exercisable—December 31, 2024	2,089,687	$ 8.18	6.50	$ 16,258

(1) The number of stock options forfeited includes those exchanged in the Option Exchange as described above.

The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of December 31, 2024. The intrinsic value of options exercised for the years ended December 31, 2024, 2023, and 2022 were $4.2 million, $1.2 million and $5.6 million, respectively.

The total grant-date fair value of the options vested during the years ended December 31, 2024, 2023, and 2022 were $4.0 million, $28.0 million and $25.8 million, respectively. The weighted-average grant-date fair value of employee options granted during the years ended December 31, 2024, 2023, and 2022 were $3.70, $8.01 and $14.08, respectively.

Restricted Stock Unit Activity

The following table summarizes information regarding the Company's RSUs:

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2023	2,929,602	$ 15.24
Granted	5,972,372	5.20
Vested	(1,722,037)	10.11
Forfeited	(1,124,850)	8.53
Unvested Balance—December 31, 2024	6,055,087	$ 8.04

The grant date fair value of an RSU equals the closing price of the Company's common stock on the grant date. RSUs generally vest equally over four years.

Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 13,509	$ 15,544	$ 13,034
Selling, general and administrative	28,221	23,269	19,648
Total stock-based compensation expense	$ 41,730	$ 38,813	$ 32,682

As of December 31, 2024, there was $23.9 million of total unrecognized compensation cost related to unvested options that are expected to vest, which is expected to be recognized over a weighted-average period of 2.2 years. As of December 31, 2024, there was $35.3 million of total unrecognized compensation cost related to RSUs that are expected to vest, which is expected to be recognized over a weighted-average period of 2.4 years.

In April 2024, in connection with the retirement of the former Chief Financial Officer, the Company modified the terms of this individual's historical stock awards. As a result of the modifications, the Company recognized $1.7 million of incremental stock compensation expense during the period, which is included in selling, general and administrative expenses.

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

Fair value of common stock—The Company uses its closing stock price as reported on Nasdaq on the grant date for the fair value of its stock.

Expected Term—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding. The Company uses the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term as it does not have sufficient prior exercise data to calculate based on historical data.

Expected Volatility— The Company uses its own historical stock price for expected volatility.

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

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

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

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	1.8 – 6.1	5.0 – 6.1	5.4 – 6.1
Expected volatility	79.1 – 83.2%	75.2 – 78.4%	77.9% – 82.1%
Risk-free interest rate	3.6 – 5.0%	3.5 – 4.7%	1.4 – 4.2%
Dividend yield	—%	—%	—%

2020 Employee Stock Purchase Plan

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

The ESPP is intended to qualify under Section 423 of the U.S. Internal Revenue Service Code of 1986, as amended. The maximum number of the Company's common stock which will be authorized for sale under the ESPP is equal to the sum of (a) 351,000 shares of common stock and (b) an annual increase on the first day of each year beginning in 2021 and ending in 2030, equal to the lesser of (i) 1% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors; provided, however, no more than 5,265,000 shares of the Company's common stock may be issued under the ESPP. Accordingly, on January 1, 2025, 2024 and 2023, the ESPP reserve increased by 1,178,480, 967,873, and 610,522 shares, respectively. As of December 31, 2024, the Company had 1,842,720 shares available for future grant under the ESPP.

Stock-based compensation expense related to the ESPP was $914,000, $942,000, and $880,000 for the years ended December 31, 2024, 2023 and 2022, respectively.

11. Income Taxes

The Company recorded income tax expense of $0.6 million during the year ended December 31, 2024. Of the $0.6 million recorded, $0.5 million was related to foreign withholding taxes on the milestone payments received in connection with the Huadong Agreement and $0.1 million was related to other foreign tax expense. The Company recorded income tax expense of $3.1 million during the year ended December 31, 2023. Of the $3.1 million recorded, $3.0 million was related to foreign withholding taxes on the up-front fee in connection with the Huadong Agreement and $0.1 million was related to foreign tax expense. The Company had no material U.S. federal income tax and state income tax expense for the years ended December 31, 2024, 2023 and 2022.

A reconciliation of loss before income taxes for domestic and foreign locations for the years ended December 31, 2024, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2024	2023	2022
United States	$ (130,372)	$ (255,653)	$ (311,458)
Foreign	(9,020)	(3,374)	—
Loss before income taxes	$ (139,392)	$ (259,027)	$ (311,458)

A reconciliation of income tax expense for the years ended December 31, 2024, 2023 and 2022 is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	799	3,113	—
Total current income tax expense	799	3,113	—
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	(152)	—	—
Total deferred income tax expense	(152)	—	—
Total income tax expense	$ 647	$ 3,113	$ —

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

	Year Ended December 31,		
	2024	2023	2022
Tax provision at U.S. statutory rate	$ (29,272)	$ (54,396)	$ (65,406)
State income taxes, net of federal benefit	(10,479)	(1,861)	(12,260)
Research and development tax and other credits	(973)	(4,834)	(2,968)
Change in valuation allowance	40,158	53,715	72,149
Permanent differences	1,660	3,547	1,224
Ducentis IPR&D	—	—	6,223
Non-deductible compensation	(558)	1,531	1,410
Withholding tax	500	3,000	—
Other	(389)	2,411	(372)
Provision for income tax	$ 647	$ 3,113	$ —

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

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 171,681	$ 152,276
Intangibles	1,400	1,196
Research and development tax credits	14,944	14,095
Research and expenditure capitalization	36,255	32,812
Accruals and reserves	16,085	5,878
Right-of-use liability	837	957
Stock-based compensation	15,761	9,620
Gross deferred tax assets	256,963	216,834
Deferred tax liabilities:		
Property and equipment	(58)	(120)
Right-of-use asset	(483)	(549)
Gross deferred tax liabilities	(541)	(669)
Net deferred tax assets	256,422	216,165
Less valuation allowance	(256,270)	(216,165)
Total deferred tax assets	$ 152	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets for the United States have been fully offset by a valuation allowance. The Company has an immaterial deferred tax asset related to foreign jurisdictions. The valuation allowance increased by approximately $40.1 million and $53.4 million during the years ended December 31, 2024 and 2023, respectively.

The Company has NOL carryforwards for federal and state income tax purposes of approximately $731.3 million and $624.1 million, respectively, as of December 31, 2024. Of the federal NOLs, $3.5 million originated before the 2018 tax year and will expire beginning in 2036. Under the Tax Cuts and Jobs Act of 2017, the remaining $727.8 million of NOLs generated after December 31, 2017 will be carried forward indefinitely and will be available to offset 80% of taxable income in future years. Of the $624.1 million in state net operating loss carryforwards, $541.9 million will begin to expire in 2027 and the remaining NOLs carry forward indefinitely. In addition, the Company has foreign NOL carry forwards of approximately $13.7 million as of December 31, 2024, which can be carried forward indefinitely.

As of December 31, 2024, the Company also had federal and California research and development tax credit carryforwards of $21.2 million and $4.9 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2037. The California research and development tax credit carryforwards are available indefinitely.

Federal and California tax laws impose significant restrictions on the utilization of NOL carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 and 383. The Company believes it has had ownership changes in the past, and may have additional ownership changes in the future. These ownership changes could limit its ability to use all of its NOL carryforwards, credit carryforwards, or other tax attributes.

The Inflation Reduction Act 2022 (IRA) which incorporates a Corporate Alternative Minimum Tax (CAMT) was signed on August 16, 2022. The changes were effective for the tax years beginning after December 31, 2022. The CAMT will require companies to compute two separate calculations for federal income tax purposes and pay

the greater of the new minimum tax or their regular tax liability. The CAMT does not currently have an impact on the Company.

Uncertain Tax Benefits

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

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

	Year Ended December 31,		
	2024	2023	2022
Beginning balance	$ 41,390	$ 42,505	$ 38,942
Increases (decreases) related to tax positions taken during a prior year	(131)	(3,097)	490
Increases related to tax positions taken during the current year	1,027	1,982	3,073
Ending balance	$ 42,286	$ 41,390	$ 42,505

Included in unrecognized tax benefits of $42.3 million at December 31, 2024 was $35.1 million of tax benefits that, if recognized, would not impact the Company's income tax benefit or effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. The Company does not expect that there will be a significant change in the unrecognized tax benefits over the next 12 months.

The Company files tax returns in the United States, state jurisdictions, Canada, and the United Kingdom. The tax years for 2016 and forward are subject to examination by the U.S. tax authorities and the tax years for 2016 and forward are subject to examination by the California tax authorities. Due to net operating loss carryforwards and research and development credits in the United States and state tax jurisdictions, all years effectively remain open. The Company is subject to examination by the tax authorities in Canada and the United Kingdom for the year ended December 31, 2022 to the present period.

It is the Company's practice to recognize interest and/or penalties related to income tax matters in income tax expense. For the years ended December 31, 2024, 2023 and 2022, the Company has not recognized any interest or penalties related to income taxes.

12. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average common shares outstanding. Pre-funded warrants to purchase 7,500,000 shares of the Company's stock were included in the weighted-average common shares outstanding used in calculating net loss per share for the years ended December 31, 2024 and 2023.

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

	As of December 31,		
	2024	2023	2022
Stock options to purchase common stock	5,342,909	7,919,699	7,476,223
Early exercised options subject to future vesting	—	—	14,853
RSUs subject to future vesting	6,055,087	2,929,602	1,576,529
ESPP shares subject to future issuance	16,338	26,368	17,046
Total	11,414,334	10,875,669	9,084,651

13. Segment Reporting

The Company has one reportable segment relating to the development and commercialization of treatments for dermatological diseases. The Company's Chief Operating Decision Maker (the CODM) is its Chief Executive Officer. The CODM evaluates financial information on a consolidated basis for the purposes of allocating resources and assessing performance.

The table below is a summary of the segment profit or loss, including significant segment expenses (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Total revenues	$ 196,542	$ 59,606	$ 3,686
Less:			
Cost of sales	17,169	4,237	442
Topical roflumilast program costs	5,210	35,607	83,030
Topical JAK inhibitor program costs	2,945	3,334	4,461
Other early-stage programs costs	11,477	5,681	1,128
Research and development compensation and personnel-related expenses	39,216	44,613	41,396
Selling, general and administrative expenses	228,908	184,628	121,757
Other segment expenses[(1)]	20,014	22,607	53,099
Total operating expenses	324,939	300,707	305,313
Operating loss	(128,397)	(241,101)	(301,627)
Other income, net	16,173	11,786	5,821
Interest expense	(27,168)	(29,712)	(15,652)
Provision for income taxes	647	3,113	—
Segment and consolidated net loss	$ (140,039)	$ (262,140)	$ (311,458)

(1) Other segment expenses include professional services related to research and development, medical affairs, depreciation and amortization expenses. Other segment expenses for the year ended December 31, 2022 includes in-process research and development (IPR&D) related to the acquisition of Ducentis in 2022.

SIGNATURES

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

ARCUTIS BIOTHERAPEUTICS, INC.

Date: February 25, 2025

By: /s/ Todd Franklin Watanabe

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

Date: February 25, 2025

By: /s/ David Topper

David Topper
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Todd Franklin Watanabe Todd Franklin Watanabe	President, Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2025
/s/ David Topper David Topper	Chief Financial Officer (Principal Accounting and Financial Officer)	February 25, 2025
/s/ Keith R. Leonard Keith R. Leonard	Director, Chairman	February 25, 2025
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri, Ph.D.	Director	February 25, 2025
/s/ Terrie Curran Terrie Curran	Director	February 25, 2025
/s/ Halley E. Gilbert Halley E. Gilbert	Director	February 25, 2025
/s/ Patrick J. Heron Patrick J. Heron	Director	February 25, 2025
/s/ Sue-Jean Lin Sue-Jean Lin	Director	February 25, 2025
/s/ Howard G. Welgus Howard G. Welgus, M.D.	Director	February 25, 2025
/s/ Neha Krishnamohan Neha Krishnamohan	Director	February 25, 2025

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-276794) of Arcutis Biotherapeutics, Inc.,

(2) Registration Statement (Form S-8 No. 333-236178) pertaining to the 2017 Equity Incentive Plan, the 2020 Equity Incentive Plan, and the 2020 Employee Stock Purchase Plan of Arcutis Biotherapeutics, Inc.,

(3) Registration Statement (Form S-8 No. 333-253155) pertaining to the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of Arcutis Biotherapeutics, Inc.,

(4) Registration Statement (Form S-8 No. 333-262902) pertaining to the 2020 Equity Incentive Plan, the 2020 Employee Stock Purchase Plan, and the 2022 Employment Inducement Incentive Plan of Arcutis Biotherapeutics, Inc.,

(5) Registration Statement (Form S-8 No. 333-270136) pertaining to the 2020 Equity Incentive Plan, the 2020 Employee Stock Purchase Plan, and the 2022 Employment Inducement Incentive Plan of Arcutis Biotherapeutics, Inc., and

(6) Registration Statement (Form S-8 No. 333-277405) pertaining to the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of Arcutis Biotherapeutics, Inc.

of our reports dated February 25, 2025, with respect to the consolidated financial statements of Arcutis Biotherapeutics, Inc. and the effectiveness of internal control over financial reporting of Arcutis Biotherapeutics, Inc. included in this Annual Report (Form 10-K) of Arcutis Biotherapeutics, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Los Angeles, California
February 25, 2025

Exhibit 31.1

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

I, Todd Franklin Watanabe, certify that:

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

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

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

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

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

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 25, 2025

By: /s/ Todd Franklin Watanabe

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

Exhibit 31.2

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

I, David Topper, certify that:

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

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

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

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

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

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 25, 2025

By: /s/ David Topper

David Topper
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Arcutis Biotherapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and David Topper, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: February 25, 2025 By: /s/ Todd Franklin Watanabe

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

Date: February 25, 2025 By: /s/ David Topper

David Topper
Chief Financial Officer
(Principal Accounting and Financial Officer)

Corporate and Stockholder Information

Management

Frank Watanabe
President and CEO

Courtney Barton
VP, Chief Compliance Officer

Patrick Burnett, MD, PhD, FAAD
Chief Medical Officer

Bethany Dudeck
Chief Technical Officer

Todd Edwards
Chief Commercial Officer

Raj Madan
Chief Digital and Information Officer

Mas Matsuda, JD
General Counsel & Corporate Secretary

Kent Taylor
SVP Sales

David Topper
Chief Financial Officer

Todd Tucker
Chief Human Resources Officer

Corporate Headquarters

Arcutis Biotherapeutics, Inc.
3027 Townsgate Road, Suite #300
Westlake Village, CA 91361
www.arcutis.com

Transfer Agent

Equiniti Trust Company
PO Box 64854
St Paul MN 55164-0854
1.800.468.9716

Independent Registered Accounting Firm

Ernst & Young LLP
Los Angeles, California

Market Information

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

Copies of our Form 10-K and proxy statement filed with the Securities and Exchange Commission and other information pertinent to our investors, including contact information for investor relations inquiries, are available on our website at **https://investors.arcutis.com/**

This document contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on The Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential to address large markets with significant unmet need; the development, approval and potential commercialization of product candidates; the potential commercial success and growth of ZORYVE in plaque psoriasis, seborrheic dermatitis, and atopic dermatitis, including market access and reimbursement, product demand growth and developments regarding gross-to-net; and the timing of regulatory filings and potential approvals. These statements are subject to substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 25, 2025, as well as any subsequent filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this document. Except as required by law, we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

ARCUTIS BIOTHERAPEUTICS

3027 Townsgate Road, Suite 300
Westlake Village, CA 91361

Corporate contact:
information@arcutis.com
805-418-5006

Investor contact:
ir@arcutis.com

For more information, visit www.arcutis.com

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ArcutisBio

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