Risk Factors Comparison 2025-02-25 to 2024-02-27 Form: 10-K

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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** ~~a limited operating history and two~~ products approved for commercial sale. We have incurred significant losses since our inception and **could** ~~expect to~~ continue to incur losses, which, together with our limited ~~operating~~ history **as a commercial- stage company** , makes it difficult to assess our future viability ~~. Our ability to comply with our minimum financing covenant raises substantial doubt about our financial viability and as to whether we will be able to continue as a going concern~~ . We are a commercial- stage biopharmaceutical company with ~~a limited operating history~~ **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 ~~operating~~ history **as a commercial- stage company** upon which you can evaluate our business and **Index to Financial Statements** 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 ~~for psoriasis, seborrheic dermatitis, and potentially atopic dermatitis later this year~~ . We have incurred losses in each year since our inception in June 2016. Our net loss for the year ended December 31, ~~2023~~ **2024** was approximately $ ~~262~~ **140** . ~~1~~ **0** million. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~981~~ **1, 121** . 9 million. We commercially launched our first product, ZORYVE cream **0. 3 %** , in August 2022 **,** ~~and launched~~ 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 ~~significant~~ 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** ~~Index to Financial Statements We~~ may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives. **Due to** ~~We are in~~ the ~~process~~ **ongoing commercialization** of **products approved for commercial sale, and our** ~~transitioning from a company with a focus on drug~~ development **strategy** ~~to a company capable of supporting commercialization in the United States and Canada. We may not be successful in this transition. On November 1, 2023, we entered into an~~ **and** ~~amendment to the Loan Agreement with SLR. Pursuant to the amendment, we agreed to an additional minimum financing covenant that requires that the Company raise $ 31. 0 million in net cash proceeds by April 1, 2024. To date, we have raised $ 5. 3 million and we are not in compliance with the minimum financing covenant. If we do not comply with the covenant, there would be an event of default under Loan Agreement and our debt could be accelerated. We intend to raise additional capital through (a) the sale or issuance of equity interests, (b) business development or collaboration agreements (including upfront, milestone, royalty and other payments), or (c) subordinated debt, in each case as permitted pursuant to the terms of the Loan Agreement. However, as our ability to raise any such additional capital is based in part on factors that are outside of our control, we cannot provide any assurance that we will be successful in raising such additional capital on commercially reasonable terms or at all. This uncertainty as to our ability to comply with the minimum financing covenant indicate that we may be unable to continue as a going concern. Our auditor' s report on our financial statements for the year ended December 31, 2023 includes an explanatory paragraph that we may be unable to continue as a going concern. Our financial statements do not include adjustments that might result from the outcome of this uncertainty. There can be no assurance that additional financing will be available or will be available on commercially reasonable terms. The inclusion of disclosures expressing substantial doubt about our ability to continue as a going concern could materially adversely affect our stock price and our ability to raise new capital or enter into business development or collaboration agreements. Due to the recently initiated commercialization of ZORYVE cream and foam, and our~~ 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** ~~our product development, other~~ operations ~~,~~ or ~~commercialization~~ 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, ~~2023~~ **2024**, we had capital resources consisting of cash, cash equivalents, and marketable securities of $ ~~271~~ **228**. ~~9~~ **0** million. In addition, as of December 31, ~~2023~~ **2024**, we had $ ~~200~~ **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 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, ~~including a minimum financing covenant,~~ 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, ~~2023~~ **2024** , we had $ ~~200~~ **100** . 0 million outstanding under our Loan Agreement. On ~~November 1~~ **August 9** , ~~2023~~ **2024** , we entered into ~~an~~ **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** (~~i~~ **the 2024 Partial Prepayment**) ~~eliminate the undrawn tranche C term loan~~ **. On October 8, 2024, we made a 2024 Partial Prepayment** of ~~up to~~ $ ~~25~~ **100** . 0 million ~~, (ii) modify the financial covenant relating to minimum net product revenue and remove the market capitalization threshold, and (iii) include an additional minimum financing covenant~~ . ~~The amended Loan Agreement provides for term loans~~ **In connection with the 2024 Partial Prepayment, we are obligated** to **pay a prepayment penalty** ~~us in an aggregate principal amount~~ of ~~up to~~ $ ~~200~~ **1** . 0 million **by June 30** , ~~which~~ **2026 and a final fee of $ 6. 95 million, representing the final fee applicable to the** amount ~~was fully drawn as~~ of **the** ~~December 31, 2023~~ **2024 Partial Prepayment, on January 1, 2027** . As ~~security for the obligations under the Loan Agreement, we granted SLR, for the benefit of the lenders,~~ a **result** ~~continuing security interest in substantially all~~ of **such 2024 Partial Prepayment** ~~our assets, including our intellectual property~~ , subject to **us** ~~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, beginning with the month ending December 31, 2023, we must generate~~ **generating a** minimum net product revenue for ~~applicable measuring~~ **the trailing six- month** ~~periods~~ **period** ~~. Pursuant to~~ **ending as of** the ~~amendment~~ **month prior** to the **borrowing date** ~~Loan Agreement, this financial covenant requires us to generate a minimum net product revenue~~ equal to ~~75~~ **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 ~~12~~ **six-** month basis ~~for the month ending December 31, 2023 and then tested on a trailing six month basis,~~ as of the end of each month ~~, for the month ending January 31, 2024 and each month thereafter~~ . 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~~ **failure by us** to deliver such annual plan on or before December 15 of the prior year **shall** ~~will result in an event of default. In addition, pursuant to the amendment to the Loan Agreement, we agreed to a minimum financing covenant to raise at least $ 31. 0 million in net cash proceeds, during the period commencing on November 1, 2023 and ending on April 1, 2024, from (i) the sale or issuance of equity interests, (ii) business development or collaboration agreements (including upfront, milestone, royalty and other payments), or (iii) subordinated debt, in each case as permitted pursuant to the terms of the Loan Agreement. To date, we have raised $ 5. 3 million towards such minimum financing covenant and, as a result, we have not yet complied with the minimum financing covenant. If we do not comply with the covenant, there would~~ be an **immediate** event of default ~~under Loan Agreement and our debt could be accelerated. We may not be able to raise such amounts and there can be no assurance that additional financing will be available or will be available on commercially reasonable terms~~ . If the debt under the Loan Agreement were accelerated due to an event of default or otherwise, we may not

have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition. If we do not have or are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern. Moreover, regardless of a potential event of default, the debt under the Loan Agreement matures and is due on ~~January~~ **August** 1, ~~2027~~ **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** ~~as a result of the reduced~~ disclosure and ~~governance~~ **reporting** requirements ~~applicable to smaller reporting companies, our common stock may be less attractive to investors. Beginning with the quarter ended June 30, 2023, we re- qualified as a smaller reporting company~~ . We are **subject** ~~therefore entitled~~ to ~~take advantage~~ **Section 404** of ~~many of~~ the ~~same exemptions from disclosure~~ **Sarbanes- Oxley Act, which generally** ~~requirements~~ ---- **requires a** ~~as an emerging growth~~ company **' s management to** ~~, including reduced disclosure obligations regarding executive compensation in our periodic reports~~ - **report upon** ~~and proxy statements. In addition, as a smaller reporting company [with annual revenue of less than $ 100 million for the year ended December 31, 2023], we qualify as a non- accelerated filer and thus are exempt from the requirement to obtain an auditor attestation on~~ the effectiveness of ~~our~~ internal control over financial reporting ~~provided in Section 404 (b) of~~ **and an independent registered public accounting firm to attest to** the ~~Sarbanes~~ **effectiveness of internal control over financial reporting in annual reports on Form 10** - **K** ~~Oxley Act of 2002, or the Sarbanes- Oxley Act~~ . ~~These exemptions and reduced disclosures~~ **However, during any period** in **which we qualified** ~~our SEC filings due to our status~~ as a smaller reporting company **, we were not required to include** ~~and~~ - **an** ~~/~~ **attestation report on internal control over financial reporting issued by** ~~or~~ **our** ~~a~~ **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 ~~may make it harder~~ **, 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 ~~investors~~ **the fiscal year ending December 31, 2024. To prepare for compliance with Section 404, we engaged in a process** to ~~analyze~~ **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 ~~and financial prospects~~ . 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** ~~We have limited experience as a commercial company and the~~ sales, marketing, and distribution of ZORYVE or any future approved products may be unsuccessful or less successful than anticipated. We ~~recently~~ began commercializing our first ~~products~~ - **product** ~~, ZORYVE cream and foam,~~ 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 ~~or delay~~ 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 ~~. Further, given our lack of experience commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product~~. 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 ~~two~~ **three** products approved for commercial sale **~~,~~ :** ZORYVE cream **0. 3 %** , ~~which is~~ a potent PDE4 inhibitor topical cream ~~that was~~ 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) **;** ~~, and~~ ZORYVE foam, ~~which is~~ a potent PDE4 inhibitor topical foam ~~that was~~ 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 ~~to treat~~ **0. 05 % for the treatment of** atopic dermatitis **in patients ages 2 to 5** ~~, and ZORYVE foam for the treatment of scalp and body psoriasis~~ , 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 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 ~~two~~ **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 ~~U. S.~~ **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** ~~foam in the U~~ . ~~S.~~ **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 $ ~~15~~ **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, ~~2023~~ **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 ~~tapinarof~~ **Vtama** , marketed by **Organon & Co** ~~Dermavant Sciences, Inc~~ .; 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~~ **, 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 ~~therapy~~ **therapies** Dupixent, marketed by Regeneron Pharmaceuticals, Inc; ~~is approved, as well as the recently approved injectable biologic therapy~~ Adbry, marketed by LEO Pharma **; and Ebglyss, marketed by Eli Lilly & Co** . Non-injectable systemic therapies RINVOQ and CIBINQO ~~were~~ **are** 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 Dermavant Sciences, Inc., 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~~ **and Litfulo (ritlecitinib), marketed by Pfizer, inc., both** oral JAK ~~inhibitor~~ **inhibitors ,** and the ~~first~~ **only** FDA-approved ~~treatment~~ **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 ~~: 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 **Anzupgo (** delgocitinib **)** , under development by LEO Pharma A / S, ~~which has reported positive Phase 3 results~~ **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** ~~PF- 06651600 and oral PF- 06700841, both~~ 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, ~~2023~~ **2024** , we had ~~296~~ **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. ~~Any~~ **Our current and future** collaboration arrangements ~~that we may enter into in the future~~ may not be successful, which could adversely affect our ability to develop and commercialize future product candidates. We **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. ~~We~~ **To the extent that we decide to enter into future collaboration agreements, we** will face ~~, to the extent that we decide to enter into collaboration agreements,~~ significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time- consuming to negotiate, document, implement, and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements ~~should we so chose to enter into such arrangements~~. The terms of any collaborations or other arrangements that we may establish may not be favorable to us. ~~Any~~ **Our current and** future collaborations ~~that we enter into~~ may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that: • collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations; • collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; • a collaborator with sales, marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities **, 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 ~~would~~ prevent us from collaborating with others; • collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated, and, if terminated, ~~this~~ may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates; • collaborators may own or co- own intellectual property covering products that ~~results~~ **result** from our collaborating with them, and in such cases, ~~we~~ would **result in us** not ~~have~~ **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 ~~following~~ any ~~such~~ collaboration ~~,~~ or other strategic transaction ~~, we~~ will achieve the expected synergies ~~to justify the transaction~~. For example, such transactions may require us to incur non- recurring or other charges, increase our near- and long- term expenditures, and pose significant integration or implementation challenges or disrupt our management or business. These transactions ~~would~~ entail numerous operational and financial risks, including exposure to unknown liabilities **, 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 ~~, acquisition or integration costs, write- downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business~~. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of 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** ~~We are subject~~ to Section 404 of the Sarbanes- Oxley Act **of 2002** , **our** ~~which generally requires a company' s~~ management **is required** to report upon the effectiveness of **our** internal control over financial reporting and ~~an~~ **, 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 ~~in~~ **beginning with this** ~~annual~~ **Annual** ~~reports~~ **Report** on Form 10- K. **The rules governing** ~~Pursuant to Section 404 (a), we are required to file with~~ the ~~SEC an annual~~ **standards that must be met for our** management **and our independent registered public accounting firm to** ~~assessment~~ ~~----~~ **assess** ~~of the effectiveness of~~ our internal control over financial reporting ~~. However, because we re- qualified as a smaller reporting company and~~ are **complex and** ~~a non- accelerated filer, we are no longer required~~ **require** ~~to comply~~ **significant documentation, testing, and possible remediation. In connection** with ~~the auditor attestation requirements regarding the effectiveness~~ **our and our independent registered public accounting firm' s evaluations** of our internal control over financial reporting ~~under~~ **, 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 ~~(b)~~ of the Sarbanes- Oxley Act ~~until we become an accelerated filer or large accelerated filer. Our management' s assessment~~ of ~~the effectiveness of~~ **2002 may reveal deficiencies in** our internal control over financial reporting ~~needs~~ **that are deemed** to **be** ~~include disclosure of any~~ material weaknesses ~~identified by our~~ **or** ~~management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such~~ that **may require prospective or retroactive changes to our** ~~there is a reasonable possibility that a material misstatement of a company' s annual and interim~~ financial statements ~~will not be detected~~ or ~~prevented on a timely basis. If we~~ identify ~~one~~ **other areas** ~~or~~ **for further attention** ~~more material weaknesses in our~~ **or improvement. Inferior** ~~internal control over financial reporting, we will be unable to assert that our~~ 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,** ~~effective. The effectiveness of our~~ **or** ~~controls and procedures may be limited by a variety of factors, including faulty human judgment and simple errors, omissions or mistakes; fraudulent action of an individual or collusion of two or more people; inappropriate management override of procedures; and the~~ **other regulatory authorities** ~~possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control. While we believe our internal control over financial reporting is currently effective~~ , **which could** ~~the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may~~ require additional ~~staffing and infrastructure investments and would increase our costs of doing business. We can give no assurance that material weaknesses in our internal control over~~ financial ~~reporting will not be identified in the future. Our failure to implement~~ and **management resources and** ~~maintain effective internal control over financial reporting~~ could result in ~~errors in~~ **fines, trading suspensions, payment of damages** ~~our~~ **or** ~~financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their~~ **other penalties** ~~implementation, could cause us to fail to meet our reporting obligations. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation~~ . 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~~ **Confidential** ~~information~~ **Information** . **Our** ~~We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our~~ information technology systems and ~~the processing, transmission, and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third- party vendors may or could have access to our confidential information. Our internal information technology systems and~~ infrastructure, and those of our current and any future **service providers, strategic partners, and other** collaborators, contractors and consultants ~~,~~ ~~and other third parties on which we rely~~ , 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, ~~cyber- attacks~~ **hacking, cyberattacks** or cyber- intrusions over the Internet, ~~attachments to emails~~ **phishing attacks and other social engineering schemes** , ~~persons inside~~ **employee theft** ~~our~~ **or** ~~organization~~ **misuse** , **human error, fraud, denial** ~~or persons with access to systems inside our~~ **or** ~~organization~~ **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** ~~personally~~ -- **personal** ~~identifiable~~ 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** ~~(CCPA) on June 28,~~ 2018, ~~which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations,~~ as **amended by** ~~well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further,~~ the California Privacy Rights Act (**collectively, the** ~~CPRA~~ **CCPA**) **requires** ~~generally went into effect in January 2023, and imposes additional data protection obligations on~~ covered businesses **that** ~~, including additional consumer rights processes~~ -- **process the personal information of California residents to** , ~~limitations~~ **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 ~~data uses~~ **the business' s behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have been passed in other states** , ~~new audit~~ **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** ~~for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could~~ **would make compliance challenging** ~~result in increased privacy and information security enforcement~~ . In the event that we are subject to or affected by HIPAA, the CCPA, ~~the CPRA~~ or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore, ~~in July 2023,~~ the **Federal Trade Commission (the " FTC ")** ~~SEC adopted new cybersecurity disclosure rules, aimed at enhancing~~ and ~~standardizing disclosures made by public~~ **many state Attorneys General continue to enforce federal and state consumer protection laws against** companies ~~regarding~~ **for online collection, use, dissemination and** ~~cybersecurity ----- security risk management~~ **practices that appear to be unfair or deceptive. For example** , ~~strategy~~ **according to the FTC** , ~~governance~~ **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 ~~incident reporting~~ **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 ~~a new~~ **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** ~~plan to secure~~ alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. Neither we nor our third- party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If either we or our manufacturers are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the commercial launch of our lead product candidates or any future product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved **, 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 ~~certification~~ **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 ~~will file~~ **filed** suit against Padagis ~~as appropriate~~ **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 ~~would~~ **sets trial at the court' s convenience, or around April 13- 17, 2026. The complaint** ~~trigger~~ **triggered** the automatic 30-month stay of FDA approval of the ANDA ~~. We~~ **, 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 ~~a~~ **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 cream for atopic dermatitis~~ , 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 ~~certification~~ **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 ~~will file~~ **filed** suit against Padagis ~~as appropriate~~ **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 ~~would~~ **sets trial at the court' s convenience, or around April 13- 17, 2026. The complaint** ~~trigger~~ **triggered** the automatic 30- month stay of FDA approval of the ANDA ~~. We~~ **, 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 ~~,~~ ~~encompassing ZORYVE~~ and ~~a~~ **beneficial pharmacokinetic parameters and** ~~method~~ **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 ~~no~~ **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** ~~over the last several~~ years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities at various points. ~~Even though the FDA has since resumed standard inspection operations, any resurgence of the virus may lead to other inspectional or administrative delays.~~ 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; • ~~a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; •~~ extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations; • expansion of eligibility criteria for Medicaid programs in certain states; • expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; • a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; • a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and • an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. 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 (~~beginning~~ **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. ~~On August 29~~ **CMS has published the negotiated prices for the initial ten drugs** , **which will first be effective in** ~~2023~~ **2026** , **and** ~~HHS announced~~ the list of the ~~first ten~~ **subsequent 15** drugs that will be subject to ~~price negotiations~~ **negotiation** . ~~HHS has issued and will continue to issue guidance implementing the IRA~~ , 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 ~~marketing~~ **commercializing** ZORYVE **,** we ~~expect~~ **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 ~~ZORYVE cream~~ **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. ~~It is uncertain if and to what extent various states will conform to federal tax laws.~~ 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~~ **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 ~~product~~ **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, ~~John Smither~~ **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 ~~have~~ **may** ~~proposed~~ **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.