UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31 , 2023

OR

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

Commission File Number 001-38692

EQUILLIUM, INC.

(Exact name of registrant as specified in its Charter)

Delaware	**82-1554746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2223 Avenida de la Playa , Suite 105	
La Jolla , CA	**92037**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 240-1200

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	EQ	The Nasdaq Capital Market

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $

16.0

million based on the closing price of the registrant's common stock on June 30, 2023 of $0.75 per share, as reported by the Nasdaq Global Market (prior to the registrant's transfer to The Nasdaq Capital Market on September 15, 2023).

As of March 20, 2024, there were

35,254,752

shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement for its 2024 annual meeting of stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2023. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Auditor Firm Id:	Auditor Name:	Auditor Location:
185	KPMG LLP	San Diego, California, United States

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our plans to research, develop and commercialize our product candidates and any future product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates in any of the indications for which we plan to develop them;
- the potential benefits, risks and timing of the transactions contemplated by the Asset Purchase Agreement dated December 5, 2022, or the Asset Purchase Agreement, entered into by us and Ono Pharmaceutical Co., Ltd., or Ono;
- our estimated timeline for announcing data from our clinical studies, for interacting with regulatory authorities, and for initiating clinical studies;
- our ability to obtain funding for our operations, including funding necessary to commence and complete the clinical studies of our product candidates;
- the success, cost, and timing of our product development activities, including our ongoing and planned clinical studies;
- the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- the size of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of any of our product candidates;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and in other territories where we may conduct business, including the clinical development and potential commercialization of our product candidates;
- the performance of our contract service providers, including Biocon Limited and other suppliers and manufacturers;
- the safety, efficacy and market success of competing therapies that are or become available;
- our ability to attract and retain key scientific or management personnel;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management's beliefs, opinions and views with respect to future events and are based on estimates, assumptions and information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New

risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should carefully read this Annual Report on Form 10-K and the documents that we reference herein and have filed as exhibits to the Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

RISK FACTORS SUMMARY

We face many risks and uncertainties, as more fully described in this section under the heading "Risk Factors." Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

- We have incurred significant losses since our inception, expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability;

- We will require substantial additional funding to continue and complete the development and any commercialization of EQ101 and EQ302, and if Ono does not exercise its option, itolizumab (EQ001), and any future product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations;

- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;

- We are highly dependent on the successful development of our current product candidates, EQ101, EQ302 and itolizumab (EQ001), and we may not be able to obtain regulatory or marketing approval for, or successfully commercialize, these product candidates in any of the indications for which we plan to develop them;

- Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical studies could result in increased costs to us, delay or limit our ability to raise capital or generate revenue and adversely affect our commercial prospects;

- Interim, topline or preliminary data from our clinical studies 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;

- We are and may become further dependent on Ono for funding the clinical development and commercialization of itolizumab (EQ001). If Ono terminates our Asset Purchase Agreement, does not exercise its option, or does not achieve the milestones specified in the Asset Purchase Agreement, our business and financial condition would be adversely impacted;

- We have licensed itolizumab from Biocon pursuant to an exclusive license agreement, which license is conditioned upon us meeting certain diligence obligations with respect to the development, regulatory approval and commercialization of itolizumab, and making significant milestone payments in connection with regulatory approval and commercial milestones as well as royalty payments;

- We have licensed the rights to itolizumab in the United States, Canada, Australia, and New Zealand. Any adverse developments that occur during any research, clinical, or commercial use of itolizumab by Biocon or third parties in other jurisdictions may affect our ability to obtain regulatory approval of or successfully commercialize itolizumab (EQ001) or otherwise adversely impact our business;

• If we are unable to obtain or protect intellectual property rights covering our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and we may not be able to compete effectively in our market;

• The manufacture of pharmaceutical products, especially biologics, is complex and we may encounter difficulties in production, distribution and delivery of our product candidates. If CMOs, including Biocon, our exclusive CMO for itolizumab (EQ001), encounter such difficulties, our ability to provide supply of our product candidates for clinical studies, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, if approved, could be delayed or stopped;

• We rely, and intend to continue to rely, on CROs to conduct our clinical studies and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects;

• We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with parties to market and sell our products, if approved, we may not be able to generate product revenue; and

• Even if our product candidates receive marketing approval in any indication, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.

PART I

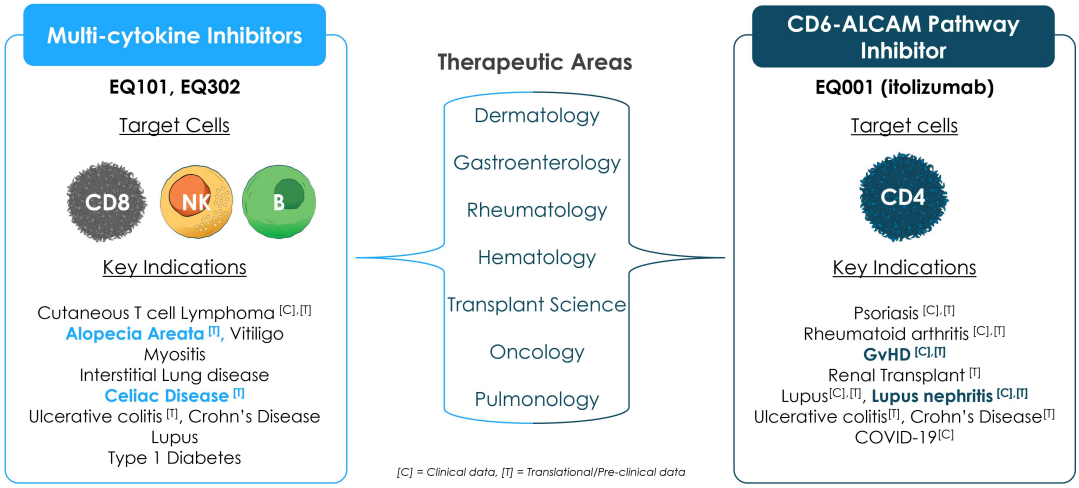
Item 1. Business.

Overview

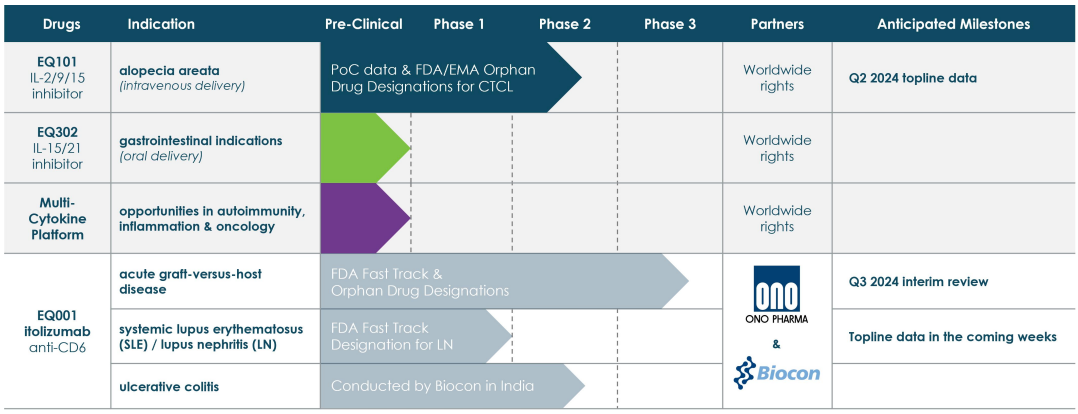
We are a clinical-stage biotechnology company leveraging a deep understanding of immunobiology to develop novel therapeutics to treat severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need. Our strategy is focused on advancing the clinical development of our product candidates, including potentially pursuing additional indications and acquiring new product candidates and platforms to expand our pipeline. We intend to commercialize our product candidates either independently or through partnerships or otherwise monetize our pipeline through strategic transactions.

Our current clinical-stage product candidates consist of EQ101 and itolizumab (EQ001). EQ101 is a first-in-class, selective, tri-specific synthetic peptide engineered to specifically inhibit IL-2, IL-9 and IL-15, key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immuno-inflammatory indications. Itolizumab (EQ001) is a first-in-class monoclonal antibody that selectively targets the immune checkpoint receptor CD6, which plays a central role in the modulation of effector T cell, or T_{eff} cell, activity and trafficking that drives a number of immuno-inflammatory diseases across multiple therapeutic areas.

We are also engaged in the discovery and optimization of additional peptide-based product candidates that selectively target multiple cytokines and are currently advancing the preclinical development of EQ302, a first-in-class, orally delivered, bi-specific inhibitor of IL-15 and IL-21. Our novel and differentiated pipeline of first-in-class immunology assets has the potential to address unmet medical needs in numerous areas, including dermatology, gastroenterology, rheumatology, hematology, transplant science, oncology and pulmonology.



We are focused on developing EQ101, EQ302 and itolizumab (EQ001) as potential best-in-class, disease modifying treatments for multiple severe immuno-inflammatory disorders. As depicted in the chart below, we currently have active clinical development programs with EQ101 and itolizumab (EQ001) and are advancing the preclinical development of EQ302. Details for each of our current clinical programs are outlined in 'Our Current Target Indications' section below.



Strategy

Our goal is to become a leading, fully-integrated biotechnology company focused on therapies for severe immuno-inflammatory disorders. To achieve our goal, we intend to:

- **Develop EQ101 for the treatment of alopecia areata.** We are conducting a Phase 2 proof-of-concept clinical study in subjects with alopecia areata, or AA. The primary objective of the study is to evaluate the safety and tolerability of EQ101 administered intravenously, or IV, with secondary objectives including the evaluation of drug efficacy, pharmacokinetic/pharmacodynamic, or PK/PD, properties, and changes in patient biomarkers. In addition, we are developing a subcutaneous, or SC, formulation of EQ101 expected to be ready for subsequent clinical studies.

- **Advance the preclinical development of EQ302.** Published research has demonstrated the synergistic effect of inhibiting both IL-15 and IL-21 as a therapeutic approach for celiac disease and potentially other autoimmune disorders. Preclinical and translational data has shown that EQ302 is a potent inhibitor of those two cytokines and is stable and permeable in the gut. We are currently conducting additional preclinical development of EQ302 to further characterize and optimize the product candidate. Pending the results, we would potentially file an Investigational New Drug, or IND, application and pursue clinical development of EQ302. Based on the unique mechanism of action of EQ302 and its product profile, including the advantage of oral delivery, we believe that EQ302 has the potential to be a compelling therapeutic for gastrointestinal diseases, such as inflammatory bowel disease and celiac disease.

- **Develop itolizumab (EQ001) for the treatment of acute graft-versus-host disease.** We are conducting EQUATOR, a pivotal Phase 3 clinical study of itolizumab (EQ001) in acute graft-versus-host disease, or aGVHD. The randomized, double-blind, placebo-controlled study will assess the efficacy and safety of itolizumab (EQ001) versus placebo as a first-line therapy for aGVHD in combination with corticosteroids.

- **Develop itolizumab (EQ001) for the treatment of lupus and lupus nephritis.** We recently completed EQUALISE, a Phase 1b proof-of-concept clinical study of itolizumab (EQ001) in patients with systemic lupus erythematosus, or SLE, and lupus nephritis, or LN. Study results, which demonstrated that itolizumab (EQ001) was well-tolerated and produced a clinically meaningful response in highly proteinuric subjects, support advancing the clinical development of itolizumab (EQ001) into later stage clinical studies for the treatment of LN and SLE.

- **Opportunistically expand our pipeline.** We will continue to conduct preclinical and translational studies and assimilate learnings from clinical studies to help inform the selection of additional indications for future development of our product candidates. We will also leverage the collective talent within our organization to opportunistically discover, acquire or in-license other high-value therapeutic programs that may complement our core strategy or have the potential for synergistic therapeutic benefit in combination with EQ101, EQ302 or itolizumab (EQ001).

- **Build a commercial infrastructure.** If any of our product candidates are approved, we may commercialize them ourselves in indications that can be effectively targeted using a specialty sales force. For other indications that require a larger sales force, we may commercialize approved products through collaborations with other parties.

Acquisition

We acquired the exclusive worldwide rights to EQ101 and a proprietary platform for discovering additional, novel multi-cytokine targeting product candidates such as EQ302 through the acquisition of Bioniz Therapeutics, Inc., or Bioniz, in February 2022. That acquisition expanded our immunology pipeline with first-in-class immuno-inflammatory product candidates across a range of development stages. See Note 6 of the Notes to Financial Statements included in this Annual Report on Form 10-K, for further details of this acquisition.

Partnerships

Option Agreement with Ono

On December 5, 2022, we entered into the Asset Purchase Agreement with Ono, pursuant to which we granted Ono the exclusive right, but not the obligation, to acquire our rights to itolizumab (EQ001), or the Option. These rights include all therapeutic indications and the rights to commercialize itolizumab (EQ001) in the United States, Canada, Australia, and New Zealand. In exchange for the Option, Ono paid us a one-time, upfront payment of an amount equal to JPY 3.5 billion, or $26.4 million.

If Ono exercises the Option, Ono will pay us a one-time, payment of an amount equal to JPY 5.0 billion, or approximately $33.1 million based on the currency exchange rate quoted by MUFG Bank, Ltd. on March 21, 2024. We expect Ono to make its option exercise decision in the second half of 2024. We are also eligible to receive up to $101.4 million upon the achievement of certain development and commercialization milestones.

We are responsible for conducting all research and development of itolizumab (EQ001), which is being funded by Ono on a quarterly basis from July 1, 2022 through the option period. Unless terminated early, the option period will expire three months following the delivery of topline data from the EQUALISE clinical study in LN and interim data from the EQUATOR Phase 3 clinical study in aGVHD.

The Asset Purchase Agreement can be terminated at any time by Ono upon written notice, provided that in limited circumstances Ono will be obligated to continue to reimburse us for research and development costs and expenses of itolizumab (EQ001) for a certain period of time following such termination. If Ono does not timely exercise its Option, the Asset Purchase Agreement and the Option will automatically terminate. The Asset Purchase Agreement also contains customary termination rights for both parties for material breach and an outside date (subject to limited adjustments) that permits either party to terminate the Asset Purchase Agreement if the closing has not occurred by December 31, 2025.

The Asset Purchase Agreement contains customary representations and warranties with respect to both Equillium and Ono. Additionally, we are subject to customary obligations and covenants, including affirmative and negative operating covenants with respect to our business as it applies to the development and exploitation of itolizumab (EQ001), exclusivity obligations that prohibit us, except in limited circumstances, including in connection with the sale of our company, from pursuing a direct or indirect sale, license or other disposition of all or any portion of our itolizumab (EQ001) program or any of the assets to be purchased pursuant to the Asset Purchase Agreement, and indemnification obligations, which, except in limited circumstances, are subject to customary caps and deductibles. See Note 9 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K, for further details of the Asset Purchase Agreement.

Collaboration and License Agreement with Biocon

We acquired the rights to itolizumab (EQ001) in May 2017, pursuant to a collaboration and license agreement with Biocon SA (subsequently assigned to Biocon Limited, or together, Biocon). Pursuant to that agreement and subsequent amendments, or Biocon License, Biocon granted us an exclusive license to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit itolizumab (EQ001) and any pharmaceutical composition or preparation containing or comprising itolizumab (EQ001) that uses Biocon technology or Biocon know-how, or collectively, a Biocon Product, in the United States, Canada, Australia and New Zealand, or the Equillium Territory. Our collaboration with Biocon includes an exclusive supply agreement for clinical and commercial drug product of itolizumab (EQ001), or the Clinical Supply Agreement. Biocon currently manufactures itolizumab (EQ001) at commercial scale in a facility in India regulated by the U.S. Food and Drug Administration, or FDA. In addition, we have agreed to co-fund an ongoing Phase 2 clinical study of itolizumab in subjects with ulcerative colitis being conducted by Biocon in India.

In consideration for the rights granted to us by Biocon, we issued to Biocon 2,316,134 shares of common stock. In addition, we are obligated to pay Biocon up to an aggregate of $30 million in regulatory milestone payments upon the achievement of certain regulatory approvals and up to an aggregate of $565 million in sales milestone payments upon the achievement of first commercial sale of product and specified levels of product sales. We are also required to pay royalties on tiers of aggregate annual net sales of Biocon Products by us, our affiliates and our sublicensees in the United States and Canada at

percentages from the mid-single digits to sub-teen double digits and on tiers of aggregate annual net sales of Biocon Products by us and our affiliates (but not our sublicensees) in Australia and New Zealand, in each case, subject to adjustments in certain circumstances. Biocon is also required to pay us royalties at comparable percentages for sales of itolizumab outside of the Equillium Territory if the approvals in such geographies included or referenced our data, including data from certain of our clinical studies, subject to adjustments in certain circumstances. Should Ono exercise its Option to acquire our rights to itolizumab (EQ001), the aforementioned milestone payments and royalties potentially owed to Biocon would become Ono's responsibility, and the potential royalties on sales of itolizumab (EQ001) outside of the Equillium Territory would become Ono's right. See Note 9 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K for further details of the Biocon License and Clinical Supply Agreement.

Understanding the Basis of Our Approach: Multi-Cytokine Inhibition

Targeted Inhibition of Disease-Associated γC Cytokines with Novel Compounds Generated from a Proprietary Discovery Platform

Our proprietary multi-cytokine platform generates rationally designed composite peptides that selectively block key cytokines at the shared receptor level targeting pathogenic cytokine redundancies and synergies while preserving non-pathogenic signaling.

This approach provides multi-cytokine inhibition at the receptor level and is expected to avoid the broad immuno-suppression and off-target safety liabilities of Janus kinase, or JAK, inhibitors. Many immune-mediated diseases are driven by the same combination of dysregulated cytokines, and we believe identifying the key cytokines for these diseases will allow us to target and develop customized treatment strategies for multiple autoimmune diseases.

Many monoclonal antibody, or mAb, therapies are targeted to a single cytokine or cytokine receptor and may not completely address the disease pathology if more than one cytokine is implicated in the disease process. Another therapeutic approach, inhibition of the Janus kinase/signal transducer and activator of transcription, or JAK/STAT, signaling pathway, lacks specificity as it inhibits a signaling pathway that is utilized by many cytokines regardless of their involvement in the disease. As a result, this class of compounds is often associated with serious side effects. Further, JAK inhibitors only inhibit the JAK/STAT signaling pathway, whereas our peptides are designed to inhibit additional pathways including PI3K and ERK. Therefore, our peptides may provide more selective yet complete inhibition of key downstream signaling pathways, which we believe has the potential to translate into a more compelling therapeutic profile. Our proprietary peptides selectively block multiple disease driving cytokines while maintaining the healthy immune balance through the normal function of other family members. See **Figure 1.**

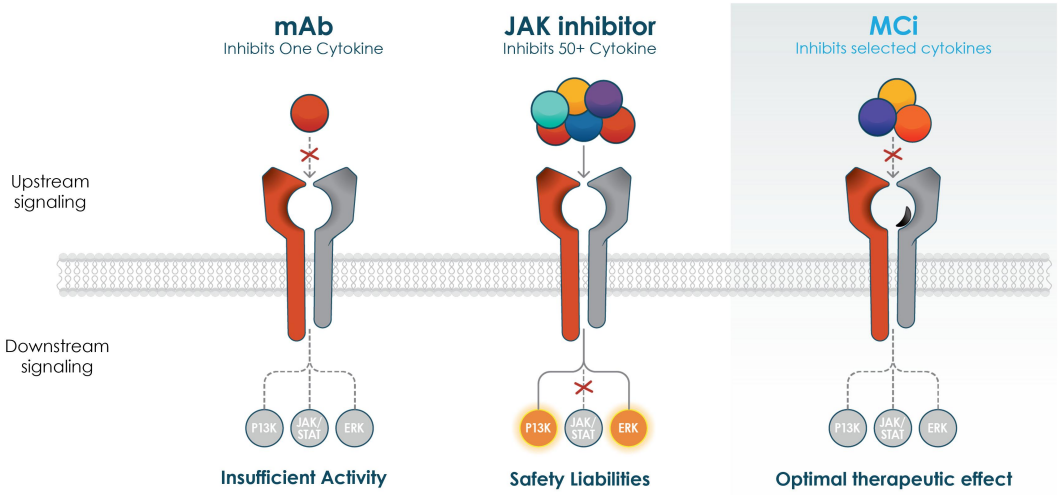


Figure 1: Rationally designed, selective inhibition of multiple cytokines is believed to represent an optimized therapeutic modality compared to mAb and JAK inhibitors.

Equillium's Multi-Cytokine Inhibitors Selectively Block Activity of Certain Cytokines by Binding Pockets in the gC Common Receptor

EQ101 is a first-in-class, tri-specific inhibitor of IL-2, IL-9 and IL-15, three inflammatory cytokines implicated in multiple diseases. It selectively blocks those three key pathogenic cytokines while preserving non-pathogenic signaling related to the other *gC* cytokine family members, IL-4, IL-7 and IL-21 (**Figure 2).** EQ101 has demonstrated clinical proof-of-concept as a novel tri-specific cytokine inhibitor through a completed Phase 1/2 clinical study in cutaneous T cell lymphoma, or CTCL, a dermato-oncology indication. The study achieved its primary objective of safety and tolerability and showed clinically meaningful improvements in the modified severity-weighted assessment tool, or SWAT, scores. In that study, the compound was shown to be well tolerated with a favorable safety profile with no drug-related serious adverse events, or SAEs, no dose-limiting toxicities, and no clinically significant laboratory abnormalities.

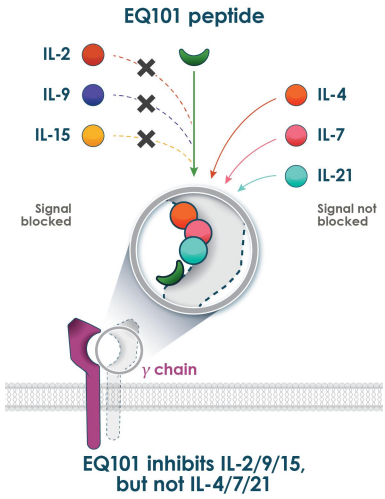


Figure 2: EQ101 inhibits IL-2, IL-9 and IL-15, but not IL-4, IL-7 or IL-21

EQ302 is a first-in-class, orally delivered, selective inhibitor of IL-15 and IL-21 (**Figure 3**). Translational and preclinical data support its potential use as a treatment for various gastrointestinal diseases including celiac disease, an immune disorder related to gluten exposure. The high degree of selectivity for IL-15 and IL-21 inhibition aligns well with the demonstrated key involvement of these two cytokines that work synergistically in driving the pathology in celiac disease and other inflammatory gut and hepatic disorders.

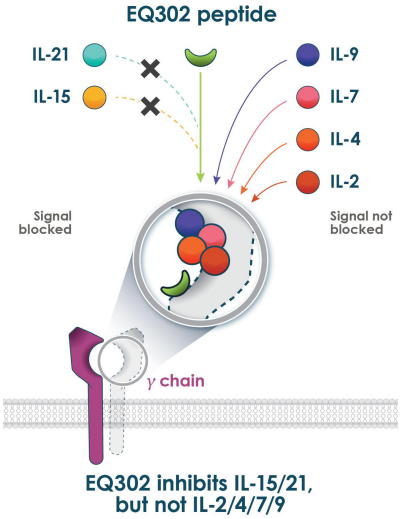


Figure 3: EQ302 inhibits IL-15 and IL-21, but not IL-2, IL-4, IL-7 or IL-9

EQ101 & EQ302 Product Development

EQ101

EQ101 is a synthetic peptide covalently conjugated to a polyethylene glycol, or PEG, molecule in a site-specific manner. The drug substance is currently manufactured under good manufacturing practices, or GMP, by a contract manufacturing organization, or CMO, located in the United States. EQ101 drug product is currently formulated as a lyophilized powder for IV injection following reconstitution with Sterile Water for Injection, or SWFI. We are developing a subcutaneous, or SC, formulation of EQ101 expected to be ready for subsequent clinical studies.

Preclinical proof-of-concept studies of EQ101 have been conducted utilizing an animal model of immune-mediated hair loss. Non-Obese-Diabetic, or NOD, severe immune-deficient, or SCID, γc (CD132)-/- (NSG) mice are deficient in lymphoid cells and were used for generating a humanized mouse model of immune-mediated hair loss, which has been used by other labs (Sonntag 2015). Humanized mice that are transplanted with human peripheral blood mononuclear cells manifest symptoms including severe systemic hair loss or alopecia. Following the development of significant alopecia, approximately 4−5 weeks post-transplant, the animals initiated study treatment. Response to treatment was evaluated using survival, body weight, serum cytokine levels (i.e., IL-2, IL-6, IL-15, TNFa, IFNγ), and hair regrowth.

The efficacy results from the intervention studies found that EQ101 blockade of IL-2, IL-9 and IL-15 signaling resulted in significant regrowth of hair in this immune-mediated hair loss mouse model of AA. In addition, EQ101 also reduced circulating levels of the inflammatory cytokines IL-6 and interferon gamma, or IFNγ, which are part of the immuno-inflammatory process observed in patients with AA. In this mouse model, EQ101 appeared to be more efficacious than an anti-IL-2 mAb, an anti-IL-15 mAb, and the JAK 1/2 inhibitor ruxolitinib. These results suggest that EQ101 has promise as a novel potential treatment for patients with AA.

EQ101 has been evaluated by Bioniz in three completed human clinical studies. One was a single ascending dose, or SAD, clinical study in healthy volunteers and another was a MAD clinical study in healthy volunteers. In the SAD study, subjects received EQ101 administered IV, at a single dose of 0.2, 0.4, 0.8, 1.6, 3.2, or 6.4 mg/kg. In the MAD study, subjects received four weekly IV doses of EQ101 at 0.5, 1, or 1.5 mg/kg or three doses every other week at 2 or 3 mg/kg. A total of 43 healthy subjects received at least 1 dose of EQ101 in each of the two studies. EQ101 was considered well-tolerated with no deaths, serious or severe treatment-emergent adverse events, infusion reactions or dose-limiting toxicities, or DLTs.

Bioniz also evaluated EQ101 in an open-label Phase 1/2 dose-ranging clinical study of patients with large granular lymphocyte leukemia, or LGLL, or refractory cutaneous T cell lymphoma, or rCTCL, to characterize the safety, tolerability, clinical efficacy, and PK/PD of EQ101. The study enrolled 50 subjects, 30 with rCTCL and 20 with LGLL. Four escalating

dose levels of 0.5 mg/kg, 1.0 mg/kg, 2.0 mg/kg and 4.0 mg/kg were administered weekly by IV infusion for up to 74 weeks. The study found that EQ101 was well-tolerated, with no DLTs, no infusion reactions, and no deaths, and only one subject discontinued participation due to an adverse event. Subjects treated with EQ101 exhibited a reduction in IL-2 and IL-15 dependent cells and inflammation, with improvements in skin lesions and a favorable overall response rate observed. Both the FDA and the European Medicines Agency, or EMA, granted EQ101 Orphan Drug designations for the treatment of CTCL in July 2019 and April 2021, respectively.

EQ302

EQ302 is a stapled peptide that uses validated hydrocarbon staple technology to stabilize the peptide while retaining its specificity and enabling an attractive drug product profile. It can be orally delivered and is both stable and permeable in the gut. We are currently performing preclinical pharmacology and formulation development of EQ302 to further characterize and optimize the product candidate.

Understanding the Basis of Our Approach: CD6-ALCAM Pathway Inhibition

The Role of CD6 in Autoimmunity

The role of the immune system is to defend the body against foreign organisms and cells, including cancerous cells, and in doing so must distinguish accurately between self- and non-self entities, a process called tolerance. Autoimmunity is an immune response directed against the body's own healthy cells and tissues, and is the underlying process in many inflammatory diseases. Autoimmunity results from a loss of tolerance caused in part by an imbalance in the relationship between T effector cells, or T_{eff} cells, and regulatory T cells, or T_{reg} cells. See **Figure 4**.

Figure 4: Autoimmunity is a balancing act. T_{reg} cells play an important role in preventing T_{eff} cells targeting of self-antigens that can lead to autoimmunity and tissue destruction.

Immune checkpoints are critical regulators of immune activation pathways, can be either co-stimulatory (activating) or co-inhibitory (inhibiting), and are crucial for maintaining immune balance and preventing autoimmunity. We believe co-stimulatory checkpoints are attractive drug targets for the treatment of immuno-inflammatory diseases, and more recently they have become a focus of development in immuno-inflammation.

CD6 is a co-stimulatory receptor that plays an integral role in modulating T cell activation, proliferation, differentiation and trafficking. CD6 serves as a key checkpoint in regulating T_{eff} cells that are central to autoimmune responses. Preclinical and clinical studies have shown that blockade of CD6 co-stimulation leads to selective inhibition of pathogenic T_{eff} cell activity and trafficking, while preserving the important regulatory function of T_{reg} cells. Such studies and new insights into the underlying biology highlight CD6 as a resurgent target for the treatment of multiple immuno-inflammatory diseases.

Activated leukocyte cell adhesion molecule, or ALCAM, is a ligand of CD6 that is expressed on hematopoietic tissues such as antigen-presenting cells, where it is important for immune synapse formation and optimal co-stimulation. Binding of ALCAM to domain-3 of CD6 leads to the downstream activation of several mitogen activated protein kinase pathways related to T cell activation, proliferation, differentiation and survival. See **Figure 5.**

ALCAM is also expressed on non-hematopoietic tissues such as the vascular endothelium, blood-brain barrier, skin, lung, kidney and gut, where it selectively facilitates the trafficking of T cells expressing CD6.

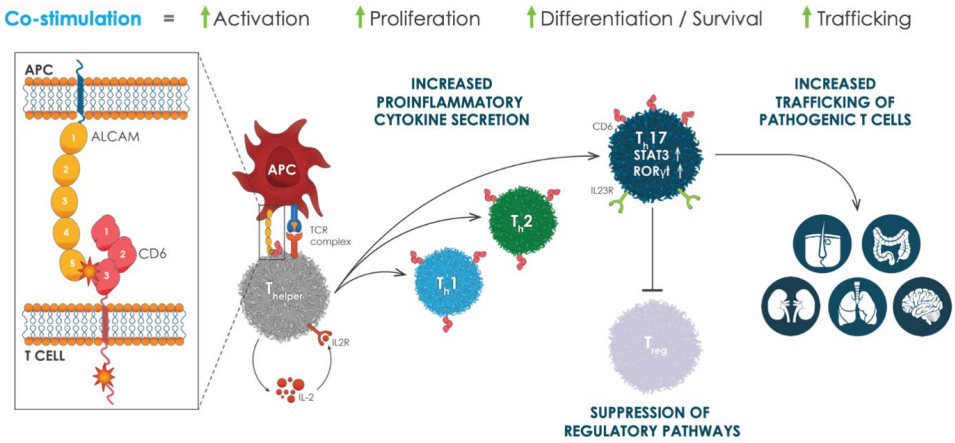


Figure 5: CD6 co-stimulation drives pathogenic T cell development and activity. Co-stimulation occurs through the binding of ALCAM to domain-3 of CD6, leading to synergistic activation resulting in a five-fold increase in IL-2 receptor mediated T_{eff} cell proliferation. Co-stimulation through CD6 promotes a pro-inflammatory response including the activation of pSTAT3 and RORγt resulting in increased expression of IL-23R and pathogenic secretion of several T_{eff} pro-inflammatory cytokines. ALCAM expressed on tissues such as the skin, lung, gut, blood-brain-barrier and kidney, selectively facilitates the trafficking of T_{eff} cells expressing CD6. Notably, T_h17 cells (that are steroid insensitive) and associated cytokines suppress T_{reg} cell activity leading to a high T_h17:T_{reg} ratio characteristic of chronic autoimmunity.

Modulation of T_{eff} Cell Activity with Itolizumab (EQ001)

Itolizumab (EQ001) is a humanized antibody that selectively binds to human CD6 and inhibits the interaction of CD6 with its ligand ALCAM, preventing co-stimulation, and thereby reducing T_{eff} cell activity and trafficking. Preclinical studies of itolizumab (EQ001) have shown that blockade of CD6 leads to a reduction in T_{eff} cell proliferation and downregulation of several important pathways that contribute to T_{eff} cell development such as Th1, Th2 and Th17 cells. Critically, CD6 blockade leads to the downregulation of important cellular pathways that control inflammation, including STAT3 and RORγt. The downregulation of these pathways is accompanied by decreased secretion of the pro-inflammatory T_{eff} cytokines IFN-γ, TNF-α, IL-6 and IL-17.

Additionally, by inhibiting the binding of ALCAM to CD6, itolizumab modulates lymphocyte trafficking and results in reduced T_{eff} cell infiltration into inflamed tissues. Based on its broad multi-modal mechanism, we believe itolizumab (EQ001) has the potential to treat multiple immuno-inflammatory diseases, including those that are resistant or refractory to existing therapies. See **Figure 6**.

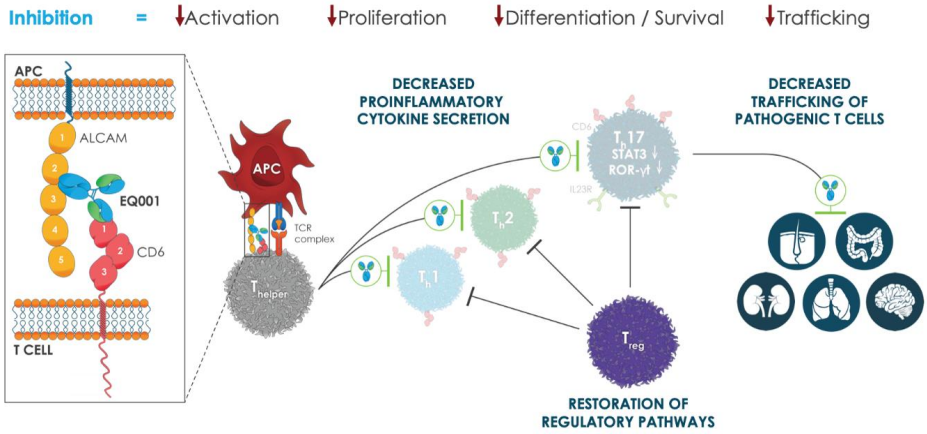


Figure 6: Blockade of CD6 by itolizumab (EQ001) inhibits T_{eff} cell activation, proliferation, differentiation and trafficking. Itolizumab (EQ001) selectively binds to domain-1 of CD6 and inhibits the interaction of ALCAM, preventing co-stimulation and thereby reducing T_{eff} cell proliferation. Blockade of CD6 downregulates pSTAT and RORγt resulting in reduced expression of IL-23R and secretion of pro-inflammatory T_{eff} cytokines IFN-γ, TNF-α, IL-6 and IL-17. Additionally, inhibiting the binding of ALCAM to CD6, reduces lymphocyte trafficking into inflamed tissues such as the skin, lung, gut, blood-brain-barrier and kidney. Reduction in the number and activity of T_h17 cells inhibiting the T_{reg} cells restores immune balance and promotes immune tolerance.

Itolizumab (EQ001) Product Development by Biocon

Itolizumab has shown clinical activity and that it was well-tolerated in completed clinical studies conducted by Biocon in patients with rheumatoid arthritis, psoriasis, and acute respiratory distress syndrome, or ARDS, related to COVID-19. Itolizumab has been approved for the treatment of moderate to severe plaque psoriasis in India where it was originally launched by Biocon under the brand name ALZUMAb. ALZUMAb was produced in an NS0 cell line and formerly available only in an IV formulation. Itolizumab (EQ001) contains the identical monoclonal antibody sequence produced in a Chinese hamster ovary, or CHO, cell line and may be administered by IV or SC. CHO cell lines are the industry-standard antibody therapeutic production system. In September 2020, the Drugs Controller General of India granted approval to Biocon of itolizumab produced in a CHO cell line, marketed by Biocon in India under the brand name ALZUMAb-L, or ALZUMAb Lyophilized, for the treatment of plaque psoriasis, as well as emergency use authorization of ALZUMAb-L for the treatment of cytokine release syndrome in COVID-19 patients with moderate to severe ARDS. ALZUMAb is no longer being manufactured by Biocon and is no longer commercially available. Biocon has transitioned their marketing and commercialization efforts from ALZUMAb to ALZUMAb-L. Itolizumab (EQ001) and ALZUMAb-L are different drug product names for the same formulation.

Itolizumab (EQ001) is manufactured by Biocon at commercial scale in an FDA regulated manufacturing facility in India. Biocon has generated data demonstrating the analytical biocomparability of itolizumab (EQ001)/ALZUMAb-L and ALZUMAb using industry-standard physicochemical and biofunctional characterization methods.

In a Phase 1 study of ALZUMAb and itolizumab (EQ001) administered both IV and SC in healthy volunteers conducted by Biocon and completed in the fourth quarter of 2017, transient, reversible grade 2 to 3 decreases in lymphocyte counts without clinical consequences were observed in some subjects, resulting in early termination of that study. No SAEs were reported and no other clinically meaningful abnormalities or trends were noted in clinical chemistry, hematology, and urinalysis parameters. While similar decreases in lymphocyte counts have not been reported with ALZUMAb previously, the timing of hematologic assessments in prior clinical studies may not have occurred at sufficiently early time-points to detect this transient response. Additionally, ALZUMAb had previously only been dosed in patients with active autoimmune disease and not healthy subjects. Importantly, the magnitude and kinetics of lymphocyte decreases were similar for itolizumab (EQ001) IV and ALZUMAb, while administration of itolizumab (EQ001) SC demonstrated milder decreases in lymphocyte counts, which would be expected based on the different PK properties of SC versus IV formulations. Furthermore, ALZUMAb had

been well-tolerated with demonstrated clinical activity in completed clinical studies in India in patients with rheumatoid arthritis and chronic plaque psoriasis, at doses ranging from 0.2 mg/kg to 1.6 mg/kg over a period of four years. Therefore, we believe the transient decreases in lymphocyte counts seen in the Phase 1 clinical study in healthy subjects represent a PD property of both itolizumab (EQ001) and ALZUMAb that will be monitored going forward, and the results of the Phase 1 clinical study support the advancement of itolizumab (EQ001) SC and IV into further clinical development in patients with immuno-inflammatory disease.

Biocon is also currently conducting a Phase 2 clinical study of ALZUMAb-L in India in subjects with ulcerative colitis, which Equillium is co-funding. The study commenced in November 2022 and consists of a randomized, double-blinded, placebo-controlled clinical study of up to 90 subjects to evaluate the safety and efficacy of ALZUMAb-L in patients with moderate to severe ulcerative colitis.

Our Current Target Indications

Alopecia Areata Market Overview

AA is an inflammatory, non-scarring autoimmune-mediated condition resulting in hair loss that has limited treatment options for those with severe disease. The condition occurs when the immune system attacks hair follicles on any hair-bearing area of the body, most frequently on the head and face. The lifetime incidence of AA is estimated at about two percent globally, while the prevalence is estimated to be 0.1% to 0.2%. AA affects men and women of all racial and ethnic groups. It has a higher prevalence in children and adolescents with 40% of cases occurring prior to age 20, and 80% before age 40. The causes of AA are not fully understood, but it is believed to result from a loss of immune privilege in the hair follicle following a triggering event (e.g., stress, infection, trauma) facilitated by IFNγ, that leads to an upregulation of inflammatory cytokine signaling resulting in autoimmune-mediated hair loss. AA is associated with other immune-mediated or autoimmune disorders such as thyroiditis, vitiligo, and atopic diseases. Approximately 50% of patients have chronic relapsing, remitting disease persisting more than 12 months and approximately 10% to 35% ultimately experience complete loss of scalp hair (alopecia totalis) or complete loss of scalp and body hair (alopecia universalis). AA has a psychosocial burden that can have a significant negative impact on health-related quality of life and has been associated with depression and anxiety.

Rationale for EQ101 for the Treatment of Alopecia Areata

IL-2, IL-9, and IL-15 have been identified as being upregulated in animal models of AA and in human biopsies of AA lesions. Studies have demonstrated cytotoxic CD8+ NKG2D+ T cells were both necessary and sufficient for the disease induction in mouse models of AA, with IL-2 increasing the number of CD8+ cells and IL-15 increasing the expression of NKG2D and the production of IFNγ by follicular epithelial cells that aberrantly transforms these T cells into cytotoxic T cells that attack the hair follicle. IL-15 released by dendritic cells and/or the follicular epithelial cells is believed to be the initiating event that promotes production of IFNγ, which leads to the initial loss of immune privilege of the hair follicle, and production of IL-2 that leads to T cell proliferation. Global transcriptional profiling of mouse and human AA skin revealed gene expression signatures indicative of cytotoxic T cell infiltration and upregulation of IL-2 and IL-15 that have been shown to promote the activation and survival of IFNγ-producing CD8+ NKG2D+ effector T cells. In addition, the pathologic activation by IL-9 of mast cells that produce and secrete Th2 cytokines (IL-5, IL-6 and IL-13) and TGFb and facilitate antigen presentation of the hair follicle to these cytotoxic T cells has been implicated in AA.

Several clinical studies have been conducted with JAK inhibitors for the treatment of AA. Initially, investigator-initiated studies using tofacitinib and ruxolitinib produced moderate response rates in small numbers of subjects that had been otherwise refractory to standard of care treatments. More recently, several industry-sponsored studies observed efficacy of JAK inhibitors in the treatment of AA using baricitinib, ritlecitinib and deuruxolitinib. Baricitinib and ritlecitinib were granted FDA approval for the treatment of AA in June 2022 and June 2023, respectively.

Despite the results of those clinical studies and the approvals of baricitinib and ritlecitinib, the efficacy of JAK inhibitors may be limited by their PK properties which can result in inadequate blockade of JAK signaling between doses and by the additional signaling pathways (PI3K, AKT, mTOR and MAPK/ERK) associated with the gc cytokines that are not inhibited by the JAK inhibitors, which can lead to an incomplete blockade of pathologic cytokine signaling. Furthermore, safety issues have been associated with JAK inhibitors, due to their wide-ranging inhibitory effects on non-disease-related cytokine signaling, which may limit their utility and acceptance by physicians and patients. We believe EQ101 is a more selective and effective inhibitor of IL-2, IL-9, and IL-15 (i.e., disease-driving cytokines), with a safer profile than JAK inhibitors, and may provide a novel therapeutic approach for the treatment of AA.

Development Plan in Alopecia Areata

We have two open INDs for EQ101 for AA and CTCL. In November 2022, we initiated a Phase 2 clinical study **(Figure 7)** of EQ101 in subjects with AA in Australia and New Zealand. In December 2023 we announced that we had completed enrollment of 36 patients in this multicenter, open-label, proof-of-concept clinical study of adult subjects between 18 and 60 years of age, with at least 35% scalp hair loss due to AA. Subjects will be dosed IV once weekly for 24 weeks with EQ101 at a dose level of 2 mg/kg, and subsequently followed for an additional four weeks. The primary objective of the study is to evaluate the safety and tolerability of EQ101 in subjects with moderate to severe AA over a 24-week treatment period. Secondary objectives will be to evaluate drug efficacy, PK/PD properties, and to assess changes in patient biomarkers. We expect to announce topline data from this study in the second quarter of 2024. We are developing a SC formulation of EQ101 for planned use in subsequent clinical studies.

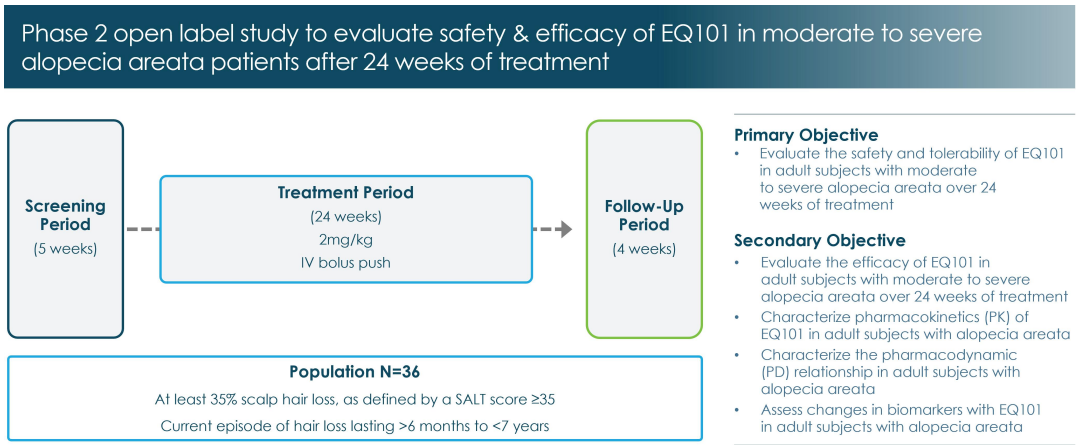


Figure 7: Phase 2 open label clinical study of EQ101 in alopecia areata

Celiac Disease Market Overview

Celiac disease is a chronic inflammatory intestinal disorder caused by inappropriate cellular and humoral immune responses to the dietary intake of gluten in the genetically susceptible individual. Celiac disease is one of the most common autoimmune disorders, with a reported prevalence of 0.5% to 1% of the global population and affecting approximately 2.3 million people in the United States. The prevalence of celiac disease has increased over the past 50 years and the rate of diagnosis has risen over the past two decades. Although celiac disease can occur at any age, onset most commonly occurs either in the first two years of life or in the second or third decades of life. Celiac disease occurs selectively in individuals expressing the gene human leukocyte antigen (HLA)-DQ2 or HLA-DQ8. In celiac disease, a mucosal inflammatory response in the intestinal epithelia leads to villous atrophy, and crypt cell hyperplasia. The loss of mucosal integrity in celiac disease is associated with a high burden of illness resulting from a plethora of intestinal and extraintestinal disease manifestations. Currently, there are no approved products to treat celiac disease, and strict adherence to a gluten-free diet is currently the only approach for celiac disease patients to manage the disease. A full recovery is often observed in pediatric celiac disease patients, but over 40% of adult celiac disease patients maintain histological abnormalities – such as villous structural damage – following complete removal of dietary gluten. Further complicating the gluten-free treatment strategy, 5% of adult patients can develop a refractory form of celiac disease, characterized by severe villous atrophy and the presence of abnormal intraepithelial lymphocytes, or IELs, which is considered the early stages of enteropathy associated T cell lymphoma, a potentially lethal condition not confined to intestinal epithelia.

Rationale for EQ302 for the Treatment of Celiac Disease

IL-15 has been identified as a key driver of celiac disease pathogenesis. IL-15 is chronically upregulated in the lamina propria and epithelium of the intestine and directly correlates with the severity of mucosal damage. This proinflammatory cytokine acts on distinct cell types resulting in malfunction of multiple immune mechanisms. Elevated IL-15 in the intestinal lamina propria has been shown to promote phenotypic changes to tolerogenic dendritic cells leading to a block in the generation of regulatory T cells, or T_{regs}, a lymphocyte subset critical for maintaining tolerance to self-antigens and promoting tolerance to innocuous dietary antigens. The reduction of inducible T_{regs} to dietary antigens elevates the potential

for an intestinal inflammatory immune response to gluten intake. IL-15 expression is also correlated with the upregulation of the activating NKG2D receptor on cytotoxic lymphocytes and its associated cytotoxic pathway, and with the complementary major histocompatibility complex class I chain-related (MIC) ligands (i.e., MICA and MICB) at the epithelial cell surface that triggers their subsequent killing by cytotoxic lymphocytes.

Another γc cytokine that has been implicated in celiac disease is IL-21. IL-21 has a robust genetic association with celiac disease. IL-21 is produced by the gluten-specific CD4 T cells in celiac disease and has the capacity to promote cytolysis in intestinal intraepithelial cytotoxic T lymphocytes (IE-CTL). IL-21 is only over-expressed in active celiac disease (patients who have gut tissue destruction) and not in potential celiac disease (those who only have antibody response and no gut tissue damage). This suggests that IL-21 may be a co-factor along with IL-15 in causing tissue damage in active celiac disease. Furthermore, IL-21 is known to be a key cytokine in the development of B cell differentiation and plasma cell generation, and therefore antibody response. A key characteristic of celiac disease is the presence of autoantibodies to transglutaminase 2 (TG2) that are produced by TG2-specific B cells. In addition to the infiltration of IE-CTLs in the lamina propria of the small bowel, there is evidence of plasmacytosis in the lamina propria which may highlight the potential pathogenic effect of autoantibody production in celiac disease. Recent studies highlighted the importance of crosstalk between CD4 T cells and B cells in activating the cytotoxic immune attack against gut tissue in celiac disease. IL-21, as a major B-cell cytokine, may play a key role in orchestrating both antibody and cytotoxic responses in celiac disease. IL-21 inhibition may control the production of autoantibodies in these patients.

Further support that these two γc cytokines work in concert is bolstered by evidence that IL-15 drives IL-21 secretion in IELs derived from patients with active celiac disease. EQ302 specifically inhibits the activity of IL-15 and IL-21, but not the remaining γc cytokines in the family (IL-2, -4, -7, or -9), thus targeting the key pathogenic cytokines in celiac disease while preserving the functional immune system through other uninterrupted γc cytokines. We believe EQ302 is uniquely positioned to provide a specific two-pronged approach to downregulate the cytotoxic activity of IELs in celiac disease by inhibiting the synergistic effect of IL-15 and IL-21. We believe EQ302 may control the gliadin mediated inflammatory effect in celiac disease by acting on both B and T cell arms in a highly selective manner.

Development Plan in Celiac Disease

We are currently conducting preclinical development of EQ302, including in vivo pharmacology and formulation development, to further characterize and optimize the product candidate. Pending positive findings, we expect to advance EQ302 into additional preclinical development to include GMP-manufacturing and toxicology studies capable of supporting a potential IND filing and advancement toward a first-in-human clinical study.

Graft-Versus-Host Disease Market Overview

Graft-versus-host disease, or GVHD, is a multisystem disorder that is a common complication of allogeneic hematopoietic stem cell transplants, or allo-HSCT, caused by the transplanted immune system, more specifically T_{eff} cells, recognizing and attacking the recipient's body. GVHD is the leading cause of non-relapse mortality in patients receiving an allo-HSCT. The risk of GVHD limits the number and type of patients receiving allo-HSCT and we believe that a therapy that can attenuate GVHD risk could significantly expand the patient population eligible for allo-HSCT.

According to the Center for International Blood & Marrow Transplant Research and other published reports, there were approximately 8,300 allo-HSCT's performed in the United States in 2021, and the number of procedures grew at an average annual growth rate of approximately 1% over the 5-year period from 2016 through 2021. In 2019, prior to the COVID-19 pandemic, there were approximately 8,600 allo-HCSTs performed. Approximately 30-70% of allo-HSCT recipients develop aGVHD. Five-year survival for patients that respond to first-line treatment with corticosteroids has been reported to be as low as 53% while in steroid refractory aGVHD, the overall 5-year survival has been reported to be as low as 5%. We estimate that the incidence of aGVHD in 2021 was approximately 4,200 patients and the total prevalence of GVHD was approximately 16,000 patients. We estimate that by the year 2030, the annual incidence of aGVHD could be up to approximately 4,500 patients and the total prevalence of GVHD could be up to approximately 20,000 patients.

Rationale for Itolizumab (EQ001) for the Treatment of GVHD

Itolizumab (EQ001) Selectively Targets GVHD Pathogenesis

There is a high unmet medical need for a safe, effective and targeted treatment of GVHD. We believe itolizumab (EQ001) has the potential to be a best-in-class treatment for aGVHD based on its ability to target the underlying biology of GVHD in a

highly selective way. Further, this approach is also promising as we consider future development in the prevention of GVHD and the treatment of chronic GVHD, or cGVHD.

It is well established that Th17 cells, driven by pSTAT3 signaling, play a role in the pathogenesis of aGVHD, and studies have shown that pSTAT3 was significantly increased in T cells of GVHD patients. In aGVHD, additional studies have reported that Th17 cells and IL-17 serum levels were significantly elevated in patients at onset compared with HSCT patients without aGVHD. As the disease progresses, Th17 cells traffic from the peripheral blood into GVHD target tissues where they trigger damage. Furthermore, the expansion of Th17 cells in the early phase of aGVHD plays a role in the transition to cGVHD. In GVHD patients, studies have shown a high Th17:T_{reg} ratio suggesting a loss of tolerance. Notably the increased number of circulating Th17 cells was accompanied by a decrease in T_{reg} cells, suggesting a loss of T_{eff} cell regulation. Such regulatory mechanisms are crucial for eliminating alloreactive T cell activity, thus preventing sustained autoimmune responses and tissue destruction in GVHD.

We believe itolizumab (EQ001) can selectively target elements of the underlying pathogenesis of aGVHD by: a) inhibiting T_{eff} cells proliferation; b) downregulating the STAT3 pathway associated with development of pathogenic Th17 cells driving GVHD pathogenesis; c) inhibiting trafficking of T_{eff} cells into GVHD target tissues preventing further inflammation and organ damage; and d) reducing the Th17:T_{reg} ratio associated with the development of GVHD and thereby promoting tolerance.

Third-party Clinical Experience with Targeting CD6 in GVHD

Clinical evidence to support the rationale of treating GVHD with itolizumab (EQ001) comes from previously-reported third-party clinical experience with CD6-expressing T cell depletion in patients receiving bone marrow transplants for hematologic malignancies where it has been demonstrated that using an anti-CD6 monoclonal antibody to deplete T cells from donor bone marrow or lymphocyte infusions has the potential to prevent aGVHD. In a study evaluating the clinical effects of selective in vitro CD6-expressing T cell depletion of donor allogeneic bone marrow using a monoclonal antibody to CD6 and rabbit complement, Soiffer et al. reported that in vitro T cell depletion with an anti-CD6 monoclonal antibody effectively reduced the incidence of both acute and chronic GVHD after allogeneic bone marrow transplant without compromising engraftment.

Subsequent studies further confirmed the feasibility of CD6-expressing T cell depletion in patients undergoing allogeneic bone marrow transplantation from human leukocyte antigen identical related and unrelated donors. In these studies, CD6- expressing depletion of the donor stem cell product was the sole method for GVHD prophylaxis. The low incidence of aGVHD reported in patients receiving allogeneic bone marrow treated with anti-CD6 monoclonal antibodies was attributed to the early appearance of a population of peripheral CD3 expressing T lymphocytes with a CD6-negative phenotype, which showed diminished reactivity to allogeneic stimulation in mixed lymphocyte reaction assays. Although the above described approach is one of ex vivo CD6-expressing T cell depletion, we believe that it further supports the role of CD6-expressing T cells in aGVHD pathogenesis and validates CD6 as a potentially important target for modulation for the treatment of GVHD.

Development Plan in aGVHD

Our IND with the FDA for aGVHD was accepted in July 2018. The FDA granted itolizumab (EQ001) Fast Track designation for the treatment of aGVHD in December 2018 and Orphan Drug designations for both the prevention and treatment of aGVHD in February 2019.

In March 2019, we initiated EQUATE**,** an open-label Phase 1b clinical study of itolizumab (EQ001) as a first-line therapy concomitant with steroids for the treatment of aGVHD. In the EQUATE clinical study, we assessed safety, PK, PD, and a number of clinical outcomes including complete response, or CR, rate, overall response rate, or ORR, survival and steroid taper.

In February 2023, we presented final safety and efficacy results from the EQUATE clinical study at the Tandem Meetings of the American Society of Transplantation and Cellular Therapy and the Center for International Blood & Marrow Transplant Research. Data was presented from a total of 30 subjects treated with itolizumab (EQ001) at doses of 0.4, 0.8, or 1.6 mg/kg. Itolizumab (EQ001) treatment in combination with systemic corticosteroids was associated with rapid and durable high rates of overall clinical response, where response at Day 29 was associated with improved progression-free survival through 1 year. Further, responders were able to taper steroids by 70% at Day 29 and 99% at Day 169. Itolizumab (EQ001) was well-tolerated in severe aGVHD patients. Based on these findings and feedback from both the FDA and leading physicians in the field of hematopoietic stem cell transplantation, in March 2022 we initiated EQUATOR, a Phase 3 pivotal clinical study in first-line aGVHD.

EQUATOR is a randomized, double-blind clinical study that will assess the efficacy and safety of itolizumab (EQ001) versus placebo as a first-line therapy for aGVHD in combination with corticosteroids. The primary objective of the study is to achieve early disease response, with key secondary objectives to evaluate durability of response, corticosteroid use, survival outcomes, and cGVHD incidence. The primary endpoint assessment is CR rate at Day 29, with key secondary endpoints of overall response rate, or ORR, at Day 29 and durability of CR rate from Day 29 through Day 99.

The EQUATOR study will compare the efficacy and safety of IV administered itolizumab (EQ001) versus placebo (randomized 1:1) as a first-line therapy in up to 200 adult and adolescent patients with Grade III-IV aGVHD or Grade II aGVHD with lower GI involvement, in combination with high doses of corticosteroids, the current standard of care. Per the study protocol, patients must receive itolizumab (EQ001) within 3 days of the first administration of high-dose corticosteroids with a treatment period from Days 1-99 and a follow-up period from Days 100-365. Eligible subjects who receive 2 mg/kg methylprednisolone or equivalent on Day 1 will be randomized in a 1:1 ratio to the following two treatment groups: Group A: itolizumab (EQ001), 1.6 mg/kg initial dose followed by 6 doses of 0.8 mg/kg once every two weeks (Q2W), plus systemic corticosteroids (100 subjects), or Group B: placebo, 7 doses Q2W, plus systemic corticosteroids (100 subjects). An independent data monitoring committee will regularly review safety data, and an interim analysis is planned after approximately 100 subjects have completed Day 29 assessments to evaluate the safety and efficacy of treatment. We anticipate that interim review occurring in the third quarter of 2024. An overview of the design of the EQUATOR study is depicted in **Figure 8**.

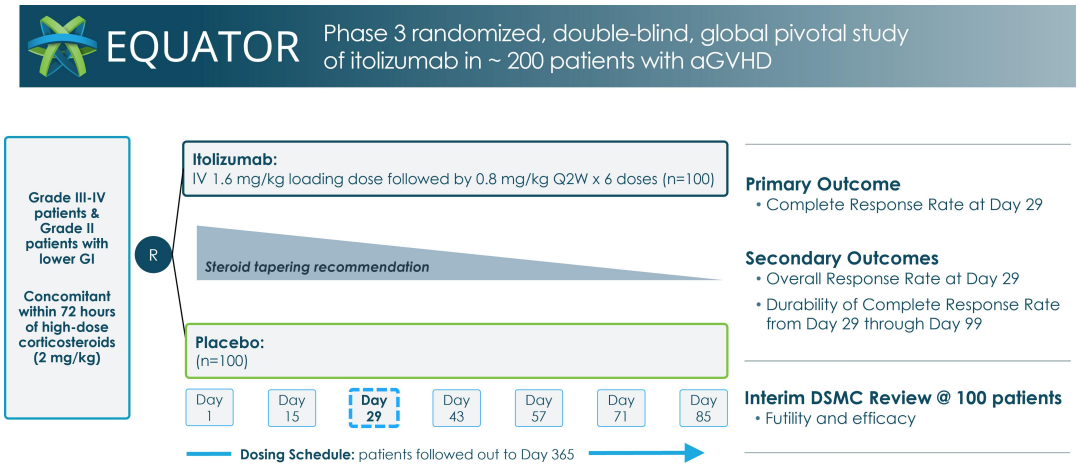


Figure 8: Overview of the EQUATOR clinical study design

Lupus Market Overview
SLE is a heterogeneous, multisystem, autoimmune disease characterized by the presence of multiple autoantibodies and deposition of immune complexes in various tissues. Based on publicly available sources, we estimate that SLE impacts between 250,000 and 322,000 people in the United States.

LN is the most frequent, serious manifestation of SLE occurring in up to 30-60% of SLE patients. It is estimated there are over 100,000 patients living with LN in the United States; despite the significant number of people affected, there are currently only two FDA-approved drugs for this condition.

Current Therapies for Lupus Nephritis and their Limitations

Current standard-of-care therapy for the most aggressive type of LN, called proliferative LN or Class III or IV LN, consists of broad-based immunosuppressive drugs, such as prednisolone, mycophenolate mofetil, or MMF, and cyclophosphamide, which come with significant toxicities. LN is predominantly a disease of young women, and these drugs carry with them a number of toxicities that are particularly problematic for this population including weight gain, edema, moon face, infection risk, diabetes, and infertility.

While these therapies have improved 5-year survival for LN patients, as many as 50-75% of patients are refractory to treatment and those that respond will likely relapse within five years. In those patients who are refractory or relapse after

initial treatment with induction therapy, there is no consensus or strong evidence to support what treatments may be effective. The prognosis for patients with proliferative LN remains poor and up to 40% of patients will progress to end-stage renal disease, or ESRD, requiring dialysis or kidney transplant. Overall, the available options are quite limited for LN patients, particularly those that are refractory to, or relapse from standard induction therapy. Two therapies are currently approved for LN. GlaxoSmithKline's Benlysta, which was approved for LN in December 2020, targets BLyS and inhibits the stimulation of autoreactive B-cells. Aurinia Pharmaceuticals, Inc.'s Lupkynis, which was approved in January 2021, is a calcineurin inhibitor that blocks IL-2 expression and inhibits autoreactive T cells. Despite those approved products, there remains a significant need for new therapies that are more effective, can maintain a durable response, and carry a better safety profile.

Rationale for Itolizumab (EQ001) for the Treatment of LN

Itolizumab (EQ001) Selectively Targets T_{eff} Cells that Play a Central Role in the Pathogenesis of LN

Despite the presence of autoantibody formation and inflammatory cytokines in SLE and LN, B cell-directed and single-cytokine targeted therapies have largely failed in clinical development. More recent evidence has demonstrated that T_{eff} cells play a central role in the pathogenesis of both SLE and LN in that they mediate tissue damage and also enhance the production of autoantibodies by promoting B cell differentiation, proliferation and maturation. Multiple T_{eff} cells/cytokines, such Th1/IFN-γ, Th2/IL-4 and Th17/IL-17, have all been implicated in the immunopathogenesis of both SLE and LN, highlighting the complex nature of the disease. However, Th17 cells are emerging as key targets as it has been demonstrated that high levels of IL-17 predict poor histopathological outcome after immunosuppressive therapy in patients with LN. Elevated levels of Th17 cells are accompanied by a decrease of T_{reg} cells, suggesting that loss of this functional immune balance may be involved in the pathogenesis of renal damage in SLE patients. Therefore, targeting T_{eff} cells, or molecules that modulate T_{eff} cell activity, while preserving T_{reg} activity could prove to be a successful therapeutic strategy for patients with SLE and LN.

We believe the unique mechanism of action of itolizumab (EQ001) can selectively target elements of the underlying pathogenesis of LN by: a) inhibiting multiple pathogenic T_{eff} cells and cytokine secretion; b) inhibiting trafficking of T_{eff} cells into kidney tissues; and c) reducing the Th17:T_{reg} ratio associated with LN.

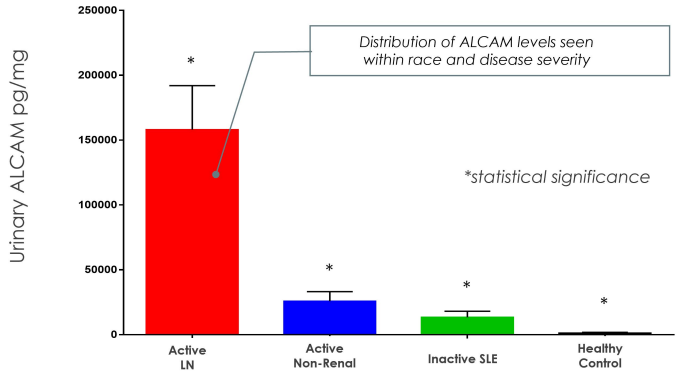
Translational Research Supporting Itolizumab (EQ001) in LN

Given the central role that T_{eff} cells play in the immunopathogenesis of SLE and LN, we believe itolizumab (EQ001), which has been shown to block the CD6-ALCAM pathway and inhibit both the activity as well as trafficking of T_{eff} cells into tissues, represents a promising therapeutic approach in this disease. To support this hypothesis, data from preclinical experiments in animal models of SLE and glomerulonephritis demonstrated that treatment with an anti-CD6 mAb lowers pro-inflammatory cytokines and improves disease activity, proteinuria, and renal function. In addition, validation for targeting the CD6-ALCAM pathway with itolizumab (EQ001) in LN is bolstered by translational research findings in human tissue and was published in the *Journal of Clinical Investigation* in January 2022. The manuscript highlights data confirming the role of T cells activated by the CD6-ALCAM pathway in the development of LN and supports our research of itolizumab (EQ001) as a potentially novel therapeutic for treating LN.

Research conducted at the University of Houston, supported by a Target Identification in Lupus Grant from the Lupus Research Alliance, has shown that patients with active LN have substantial elevations in urinary ALCAM and that ALCAM levels in the urine track with disease activity. See **Figure 9**. These data further highlight the potentially important pathogenic role of the CD6-ALCAM pathway in patients with LN.

Unbiased screening of >1100 urinary proteins identified urinary ALCAM as a strong predictor of disease activity and correlates with increased tissue expression in lupus nephritis patients

Urinary ALCAM Elevated in Active Lupus Nephritis



Urinary Biomarker Outperforms Standard Disease Biomarkers in Lupus Nephritis*

	AUC (95% CI)	P value	Sensitivity	Specificity	PPV	NPV
Urinary ALCAM	**0.91 (0.86 – 0.96)**	**< 0.0001**	**0.91**	**0.82**	**0.88**	**0.86**
Positive anti-dsDNA	NA		0.38	0.57	0.57	0.38
Low complement	NA		0.56	0.55	0.65	0.46

*Performance of urinary protein markers in differentiating active lupus nephritis (N=89) from inactive lupus nephritis (N=60) in African American and Hispanic systemic lupus erythematosus patients - UT Southwestern Medical Center, TX

Stanley et al., 2016. Comprehensive Aptamer-Based Screening of 1129 Proteins Reveals Novel Urinary Biomarkers of Lupus Nephritis. ACR/ARHP Annual Meeting. Single cell RNA sequencing data provided by the Accelerated Medicines Partnership (AMP).

Figure 9: ALCAM is a predictive biomarker in patients with active LN. The graph depicts levels of ALCAM in the urine of active LN, active (non-renal) SLE, inactive SLE and healthy controls by ELISA. ALCAM was highest in active LN patients while SLE patients were higher than healthy controls. The table compares the performance of urinary protein markers in differentiating active LN (N=89) from inactive LN (N=60) in African-American and Hispanic systemic lupus erythematosus patients.

In addition to target validation, this research on urinary biomarkers may also have important implications in how we develop itolizumab (EQ001) in LN. The ease and scalability of using urine as a non-invasive liquid biopsy of the kidney provides us an opportunity to potentially change the way we identify and treat patients with LN. A biomarker-guided treatment approach using real-time urinary testing of the CD6-ALCAM pathway to determine the right patients for therapy, guide treatment, and monitor the disease has the potential to increase the chance of advancing a targeted therapeutic to drug approval and significantly improve patient care. Specifically, elevations in urinary biomarkers, such as soluble ALCAM or CD6, could be used to identify patients most likely to respond to itolizumab (EQ001). An evaluation of these biomarkers will be an important part of the development program and forms the initial basis for exploring a personalized medicine biomarker strategy with itolizumab (EQ001).

Development Plan in LN

In July 2019, our IND for lupus/LN was accepted by the FDA, and in December 2019 the FDA granted itolizumab (EQ001) Fast Track designation for the treatment of LN. In September 2019, we initiated EQUALISE, a Phase 1b proof-of-concept clinical study of itolizumab (EQ001) in patients with SLE and in patients with LN. The Type A portion was a MAD study involving 35 SLE patients to evaluate the safety, tolerability, PK, PD, and clinical activity of SC doses of itolizumab (EQ001) ranging from 0.4 mg/kg to 3.2 mg/kg Q2W. The Type B portion of the study was open label and evaluated 17 newly

diagnosed or refractory LN patients treated with itolizumab (EQ001) dosed at 1.6 mg/kg SC Q2W for up to 24 weeks. The selection of the 1.6 mg/kg dose was based on the totality of the safety, tolerability and PK/PD data in the Type A part of the study that demonstrated a plateau in the reduction of CD6 cell surface expression above the 1.6 mg/kg dose. In addition to the same objectives as were in the Type A portion of the study, the Type B portion also assessed potential clinical activity of itolizumab (EQ001) in LN patients based on proteinuria levels and SLEDAI-2K scores. An overview of the design of the EQUALISE study is depicted in **Figure 10**.

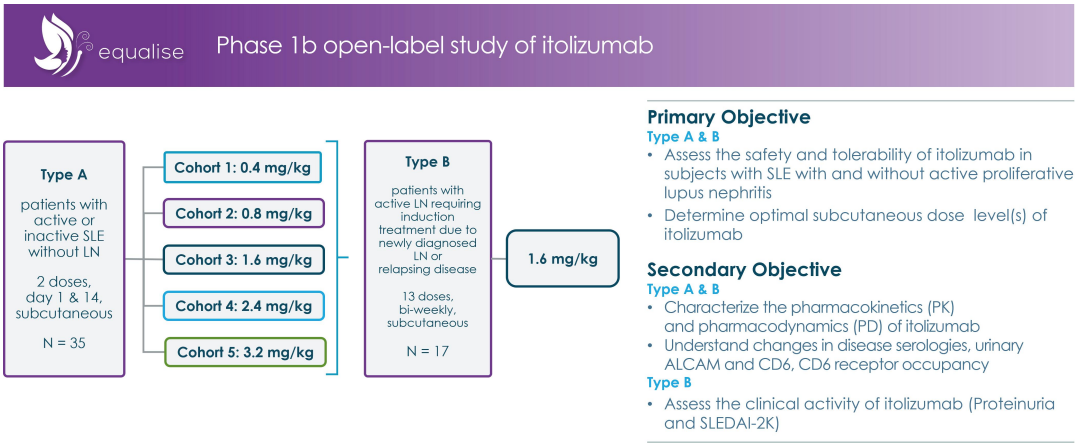


Figure 10: Overview of the EQUALISE clinical study design

In March 2021, we reported favorable topline data from the Type A group of the EQUALISE study in patients with SLE where the data showed itolizumab (EQ001) was well tolerated. In addition, itolizumab (EQ001) demonstrated a dose-dependent reduction of cell surface CD6 expression on effector T cells, an indicator of drug activity, consistent with its mechanism of action.

Following completion of study enrollment in the Type B group, in November 2023 we announced data from that portion of the study presented at the annual meetings of the American College of Rheumatology and the American Society of Nephrology. That data represented all but the last patient in the follow up period and a preview of the topline data that is expected to be delivered in the coming weeks to Ono. The data highlighted that itolizumab (EQ001) when added to MMF and corticosteroids produced high complete and partial response rates with rapid and deep reduction in urine protein creatinine ratio, or UPCR, in highly proteinuric subjects having a mean baseline UPCR of 4.9 g/g. Specifically, 73% of subjects achieved a greater than 50% reduction in UPCR by week 28, of which 40% were complete responses where UPCR was lowered below 0.7 g/g. Further, consistent with the decline in UPCR over time, subjects were able to taper their systemic corticosteroids over the course of the study. Itolizumab (EQ001) treatment was associated with reductions in absolute lymphocyte counts, or ALC, a known pharmacodynamic effect. Reductions in observed ALC were not associated with increased rates of infection or other adverse clinical signals. Two subjects had at least one serious adverse event, and study investigators assessed 77% of treatment emergent adverse events as mild (Grade 1) or moderate (Grade 2).

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, discovery platforms, novel biological discoveries, epitopes, new therapeutic approaches and potential indications, and other inventions that are important to our business. For our product candidates, generally we intend to initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including claims targeting newly identified compositional improvements, methods of design, methods of treating and additional therapeutic targets.

As of March 15, 2024, our patent portfolio related to itolizumab included issued patents and pending patent applications exclusively licensed from Biocon in the United States, Australia, Canada, and New Zealand, and pending international and national stage patent applications filed under the Patent Cooperation Treaty, or PCT, that we own. The terms of the Biocon License are discussed above in “Business—Partnerships—Collaboration and License Agreement with Biocon”.

Specifically, as of March 15, 2024, our licensed rights from Biocon relating to itolizumab included nine issued patents in the United States, six issued patents in Australia, five issued patents in Canada, six issued patents in New Zealand, and pending patent applications in the United States, Australia, Canada, and New Zealand. Five of our issued U.S. patents are expected to expire in 2028 (absent any patent term extension for regulatory delays) and include claims directed to the antibody sequence of itolizumab and methods of formulating and using itolizumab alone or in combination with other agents to treat various T cell mediated diseases and disorders including GVHD and transplant rejection. Two of our issued U.S. patents are expected to expire in 2034 (absent any patent term extension for regulatory delays), and include claims directed to treating multiple sclerosis or inflammatory bowel disease with itolizumab in certain patients exhibiting increased numbers of T_h17 cells, wherein certain of the methods include monitoring IL-23R expression. Our issued Australia, Canadian, and New Zealand patents are expected to expire between 2027 and 2034. Our licensed rights from Biocon include a pending patent application family related to methods of using itolizumab to treat lupus, which includes one issued U.S. patent and pending applications in the United States, Australia, Canada, and New Zealand. Our licensed rights from Biocon also include a pending patent application family related to methods of using itolizumab to prevent cellular and organ damage resulting from hyper-inflammatory responses to highly invasive medical procedures, which includes pending applications in the United States and Canada and expected filings in Australia and New Zealand. Patents that may issue from our pending in-licensed patent applications are expected to expire between 2028 and 2042, absent any patent term adjustments or extensions.

Additionally, we own one patent application family related to methods of using itolizumab to treat severe asthma, which is pending in the United States, Australia, Canada, and New Zealand. If granted, any patents that issue from this patent family are expected to expire in 2039, absent any patent term adjustments or extensions. We also own one patent family related to itolizumab dosing regimens, companion biomarkers, in vitro test lot assays, and ex vivo transplant therapies, which is pending in the United States, Australia, Canada, and New Zealand. If granted, any patents that issue from this patent family are expected to expire in 2041, absent any patent term adjustments or extensions.

We also co-own one pending patent application family with the University of Houston System, which relates to diagnostic methods for using itolizumab to treat LN and is pending in the United States, Australia, Canada, and New Zealand. If granted, any patents that issue from this patent family are expected to expire in 2040, absent any patent term adjustments or extensions.

As of March 15, 2024, through our acquisition of Bioniz, we wholly own a patent portfolio directed to composite peptide antagonists. This wing of our portfolio includes six additional patent application families, including those related to the IL-2, IL-9, IL-15 peptide antagonist EQ101, the IL-15 and IL-21 peptide antagonist EQ302, other peptide sequences, and other related technologies for peptide modulation of multi-cytokine signaling largely in the γc-cytokine family space.

Of these six composite peptide patent application families, the first family includes claims currently directed to composite peptides covering EQ101, methods of designing such peptides, and methods of using such peptides to treat various T cell mediated diseases and disorders (including but not limited to RA, immune-mediated hair loss, and myositis). This family currently includes nine issued U.S patents, three issued Australian patents, one issued Canadian patent, one issued Brazilian patent, one issued Chinese patent, 38 patents in European states, and two issued Japanese patents. Also pending are applications in the United States, China, Europe, Hong Kong, and Japan. If granted, any patents in this patent family are expected to expire in 2032, absent any patent term adjustments or extensions.

The second patent application family in our composite peptide portfolio includes claims currently directed to other multi-cytokine family peptide antagonists, as well as their methods of production. This family includes three issued U.S. patents and a pending U.S. application. If granted, any patents in this patent family are expected to expire in 2034, absent any patent term adjustments or extensions.

The third patent application family includes claims currently directed to composite peptides covering IL-15 and IL-21 peptide antagonists and methods of use to treat various T cell mediated diseases and disorders (including but not limited to celiac disease and inflammatory bowel disease). This family includes three issued U.S. patents, two issued Australian patents, 24 patents in European states, one issued Hong Kong patent, one issued Japanese patent, one issued Indian patent, and one issued Korean patent. Also pending are applications in the United States, Australia, Canada, China, Europe, Hong Kong, India Japan, and Korea. If granted, any patents in this patent family are expected to expire in 2036, absent any patent term adjustments or extensions.

The fourth patent application family includes claims currently directed to composite peptides covering EQ302 and methods of use to treat various T cell mediated diseases and disorders (including but not limited to celiac disease and inflammatory bowel disease). This family includes one issued Australian patent, with pending applications in the United States, Australia, Canada, China, Europe, Hong Kong, India, Japan, and Korea. If granted, any patents in this patent family are expected to expire in 2038, absent any patent term adjustments or extensions.

The fifth and sixth patent application families include claims currently directed to EQ101 for use in methods of treating various therapeutic targets including, but not limited to, alopecia areata, cytokine release syndrome, and related disorders to each. Collectively, these families include pending applications in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, and Korea. If granted, any patents in this patent family are expected to expire in either 2040 or 2041, absent any patent term adjustments or extensions.

We file U.S. provisional patent applications as well as U.S. non-provisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the 153 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of 2½ years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first 2½ years of filing.

We intend to prosecute the pending applications that we own and in-license and to pursue patent issuance and protection in key commercial markets where we expect significant product sales may occur.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a Biologics License Application, or BLA.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our products and services. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future technology may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office, or USPTO, to determine priority of invention. For a more comprehensive discussion of the risks related to our intellectual property, please see “Risk Factors—Risks Related to Intellectual Property.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application related to the patent. A U.S. patent also may be afforded a patent term adjustment, or PTA, under certain circumstances to

compensate for delays in obtaining the patent from the USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We also rely on trade secrets relating to product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, including through breaches of such agreements with our employees and consultants. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Moreover, there are several companies marketing or developing treatments that may be approved for the same indications and/or diseases as our product candidates.

Alopecia Areata

The management of AA currently involves the use of a variety of topical, intralesional, and systemic agents, as well as devices, but the response to treatment varies widely. First-line therapies typically rely on topical or intralesional corticosteroids and in more severe patients, systemic corticosteroids. For refractory disease, immunosuppressive agents such as methotrexate, azathioprine and cyclosporine may be used. There are currently only two products approved by the FDA for the treatment of AA: baricitinib, a JAK inhibitor with a brand name of Olumiant, and ritlecitinib, a JAK inhibitor with a brand name of Litfulo. Clinical studies have studied JAK inhibitors and S1P modulators, among others. Companies involved in alopecia areata drug development include Arcutis Biotherapeutics, Inc., ASLAN Pharmaceuticals Limited, Bristol-Myers Squibb Company, Concert Pharmaceuticals, Inc. (acquired by Sun Pharmaceutical Industries Ltd.), Forte Biosciences, Inc., Horizon Therapeutics plc (acquired by Amgen Inc.), Inmagene Biopharmaceutical Co. Ltd., Legacy Healthcare, Nektar

Therapeutics, Ornovio, Inc., Pfizer Inc., Q32 Bio Inc., Reistone Biopharma, Zelgen Biopharmaceuticals Co., Ltd., and Zura Bio Limited.

Celiac Disease

The only available treatment for celiac disease is lifelong adherence to a strict gluten-free diet. Most patients have difficulty maintaining such a diet and many patients do not fully respond, with symptoms persisting despite avoidance of gluten. There are currently no FDA-approved therapies for treatment of celiac disease. We are aware of a number of companies with development programs targeting the condition including Amgen Inc. (former asset of Provention Bio), Anokion SA, Calypso Biotech BV (acquired by Novartis AG), Chugai Pharmaceutical Co., Ltd., IGY Immune Technologies & Life Sciences Inc., Immunic, Inc., ImmunogenX, Inc., Protagonist Therapeutics, Inc., Takeda Pharmaceuticals, Teva Pharmaceuticals, Topas Therapeutics GmbH, and Zedira GmbH.

aGVHD

Corticosteroids, or steroids, remain the standard of care for the first-line treatment of aGVHD. There are currently no FDA-approved therapies indicated as a first-line treatment of aGVHD. Second-line therapy consists of off-label immunosuppressives for which the therapeutic benefit has not been established, and Incyte Corporation's ruxolitinib which was approved for the treatment of steroid refractory aGVHD in 2019.

In addition, we are aware of a number of companies with development programs in first-line and steroid refractory aGVHD, including AltruBio, Inc., ASC Therapeutics, CSL Behring LLC, Cynata Therapeutics Limited, ElsaLys Biotech, Evive Biotech (subsidiary of Yifan Pharmaceutical Co., Ltd.), Humanigen, Inc., Maat Pharma SA, Medac GmbH, Mesoblast Limited, Shenzhen Xbiome Biotech, Co., Ltd., TR1X Bio, VectivBio Holding AG (acquired by Ironwood Pharmaceuticals, Inc.), ViGenCell Inc., and Zelgen Biopharmaceuticals Co., Ltd.

Lupus Nephritis

Standard of care induction treatment in patients with the most severe forms of LN, called proliferative LN or Class III or IV LN, is typically IV methylprednisolone followed by oral prednisone with the addition of MMF or cyclophosphamide. Standard of care for maintenance therapy is typically a combination of corticosteroids and MMF or calcineurin inhibitors. There are currently two approved therapies for the treatment of LN. One is GlaxoSmithKline's Benlysta (belimumab), approved in 2020, and the other is Lupkynis (voclosporin), which was approved in January 2021 and is marketed by Aurinia Pharmaceuticals Inc.

We are aware of a number of companies with development programs targeting LN including AstraZeneca plc, Corestem Co., Ltd., CSL Behring LLC, Genentech Inc., Jansen Pharmaceutical Companies of Johnson & Johnson, Kezar Life Sciences, Inc., Nkarta, Inc., Novartis AG, Omeros Corporation and Vera Therapeutics, Inc.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We expect to manage sales, marketing, patient access and distribution either through internal resources or through third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities. Should Ono exercise its option to acquire our rights to itolizumab (EQ001), the commercialization of itolizumab (EQ001) would be Ono's responsibility.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We rely on CMOs to manufacture EQ101 and EQ302. We rely on Biocon, our contract manufacturer, pursuant to the Biocon License and Biocon Supply Agreement, for all our required raw materials, drug substance and drug product needs for preclinical research, clinical studies and commercial supply of itolizumab (EQ001). Biocon manufactures itolizumab (EQ001) at commercial scale at its FDA-regulated facility in Bangalore, India.

With respect to any future product candidates, we expect to rely on contract manufacturers for all our required raw materials, drug substance and drug product needs for preclinical research, clinical studies and commercial supply.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety,

effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

In the United States, the FDA regulates biologics under both the Federal Food, Drug and Cosmetic Act, or FDCA, and the Public Health Services Act, or PHSA, and their implementing regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical studies may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the study is commenced;
- performance of adequate and well-controlled human clinical studies to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application, or BLA, for product candidates that are manufactured in biological systems like itolizumab (EQ001), or a New Drug Application, or NDA, for product candidates like EQ101 or EQ302 that are manufactured through chemical synthesis, after completion of all pivotal clinical studies that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical studies;
- a determination by the FDA within 60 days of its receipt of a BLA or NDA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current good manufacturing practice, or cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval, or licensure, of the BLA or NDA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical study with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical studies may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical study. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical study can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical study.

Clinical studies involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical study conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical study must review and approve the plan for any clinical study and its informed consent form before the clinical study begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor

may suspend a clinical study at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the study is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical study if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical study results to public registries.

For purposes of BLA or NDA approval, human clinical studies are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical studies may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical studies.

- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical studies after a product is approved to gain more information about the product. These so-called Phase 4 clinical study may be made a condition to approval of the BLA or NDA. Concurrent with clinical studies, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Submission, Review and Approval of a BLA or NDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical studies are submitted to the FDA as part of a BLA or NDA requesting approval to market the product for one or more indications. The BLA or NDA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA or NDA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA or NDA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA or NDA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA or an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA or an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA or an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA or NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA or NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA or NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA or NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

Any marketing application for a new therapeutic product submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy and accelerated approval.

A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA or NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA or NDA.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical

benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan designation must be requested before submitting a BLA or NDA. After the FDA grants orphan designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full BLA or NDA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA or NDA application fee.

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

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA or NDA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, mandated modification of promotional materials or issuance of corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or complete withdrawal of the product from the market or product recalls;

- fines, warning or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

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

Regulation of Diagnostic Tests

The co-development and validation of a diagnostic marker related to the CD6-ALCAM pathway and other urinary biomarkers for a companion diagnostic to identify LN patients most likely to respond to itolizumab (EQ001) will subject us and any diagnostic collaborator to device regulations of the FDA. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. We expect that any companion diagnostic developed for itolizumab (EQ001) will utilize the PMA pathway.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, a companion diagnostic device and its corresponding drug should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, signed into law in 2010, includes the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and clinical studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a

full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical studies to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA (discussed below).

The federal false claims, including the FCA, and civil monetary penalty laws, which can be enforced by private citizens, on behalf of the government, through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain

healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements on covered entities, business associates and their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians, as defined by such law, other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report timely and accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we will need to comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical studies and other activities, and/or register their sales and medical representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit

certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare & Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop. Additionally, we or our collaborators may develop companion diagnostic tests for use with our

product candidates. Companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical products, will apply to companion diagnostics.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of biopharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The Inflation Reduction Act of 2022, or IRA, which was passed into law in August 2022, included drug pricing reforms that have the potential to adversely impact our ability to successfully commercialize our product candidates and could lessen the real or perceived value of our product candidates, which would negatively impact our business. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. For example, the Affordable Care Act: increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid-managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs; implemented 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; expanded eligibility criteria for Medicaid programs; created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS, or CMMI, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. There have been legal and political challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, President Biden signed the IRA into law which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

There have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the Trump administration signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act.

We anticipate that the Affordable Care Act, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by CMMI which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control biopharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with

accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Government Regulations Related to Economic Sanctions

Pursuant to various laws, regulations, and executive orders, the U.S. Treasury Department's Office of Foreign Assets Control, or OFAC, administers and enforces economic and trade sanctions that prohibit or restrict certain activities with embargoed countries, sanctioned entities, and sanctioned individuals for particular foreign policy and national security reasons. The scope of the sanctions varies significantly, but may include comprehensive restrictions on imports, exports, investment, and facilitation of foreign transactions involving a sanctioned jurisdiction, entity or person, as well as non-sanctioned persons and entities acting on behalf of sanctioned jurisdictions, entities or people.

One such set of regulations is the Cuban Assets Control Regulations, or CACR. The CACR prohibits U.S. persons from engaging in virtually all transactions involving property of the government of Cuba or Cuban nationals, or property in which the government of Cuba or any Cuban national has at any time on or since July 8, 1963 had any interest of any nature whatsoever, direct or indirect. Where activity is prohibited by the CACR, engagement in such activity must be authorized by a general or specific license granted by OFAC. The antibody sequence for both itolizumab (EQ001) and ALZUMAb was developed exclusively by Cuban nationals. We currently rely on a general license in the CACR, relating to Cuban-origin pharmaceuticals, to import and conduct clinical studies relating to itolizumab (EQ001).

In November 2019, OFAC notified us that after careful consideration, which included consultation with the FDA, OFAC determined that itolizumab falls within the definition of "Cuban-origin pharmaceutical" and, as such, the general licenses at section 515.547(b) and (c) of the CACR authorize the conduct of clinical studies for itolizumab for the purpose of seeking approval for the drug from the FDA. Thus, no further authorization is required from OFAC at this time for our ongoing and planned clinical studies of itolizumab.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2023, we employed 44 employees, all of whom were full-time and engaged in research and development activities, operations, finance, business development or administration. We also engage temporary employees and consultants as needed.

Corporate Information

We were originally incorporated as Attenuate Biopharmaceuticals, Inc. in Delaware in March 2017 and subsequently changed our name to Equillium, Inc. in May 2017. Our principal executive offices are located at 2223 Avenida de la Playa, Suite 105, La Jolla, CA 92037. We have two wholly-owned subsidiaries, Bioniz Therapeutics, Inc., a Delaware corporation, and Equillium Australia Pty LTD, an Australian proprietary limited corporation. Our telephone number is (858) 240-1200. Our website address is www.equilliumbio.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to such reports filed or furnished pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on our website as soon as reasonably practical after we electronically file such material with, or furnish it to, the SEC.

We are also a "smaller reporting company" as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this Annual Report on Form 10-K is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Item 1A. Risk Factors.

RISK FACTORS

You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the factors described as well as the other information in our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" when evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investments. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception, expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company incorporated in March 2017 and our operations, to date, have consisted of organizing and staffing our company, business planning, raising capital, in-licensing rights to itolizumab (EQ001), conducting non-clinical research, including the initial preclinical development of EQ302, filing three INDs, conducting clinical development of EQ101, EQ102 and itolizumab (EQ001), conducting business development activities such as the acquisition of Bioniz in February 2022 and the Asset Purchase Agreement with Ono in December 2022, and the general and administrative activities associated with being a public company. We have never completed the development of any product candidate through to marketing approval, and we have never generated any revenue from sales of an approved product. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues from sales of an approved product, and we cannot estimate with precision the extent of our future losses. For the years ended December 31, 2023 and 2022, our net losses were $13.3 million and $62.4 million, respectively. As of December 31, 2023, we had an accumulated deficit of $185.7 million. We expect to incur operating losses for the foreseeable future as we execute our plan to perform research and development activities, advance the clinical development of EQ101 and itolizumab (EQ001), conduct preclinical research and potential clinical development of EQ302 and other preclinical product candidates, perform discovery research, conduct formulation and device development of our product candidates, potentially expand the indications for which we conduct clinical development of our product candidates, potentially acquire or develop new products and/or product candidates, seek regulatory approvals of and potentially commercialize any approved products, hire and retain additional personnel, maintain compliance with regulatory requirements, protect our intellectual property, and manage the administrative aspects of our business. Furthermore, in connection with the acquisition of Bioniz, we expanded our pipeline from one product candidate to multiple product candidates, all at various stages of development. This expansion of our pipeline may accelerate the rate at which our operating losses increase as we incur costs to further the development and seek regulatory approval of these product candidates. In addition, if we obtain regulatory approval of any of our product candidates, we expect to incur increased sales and marketing expenses, with certain of such investments potentially being made in advance of an approval. As a result, we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

To become and remain profitable, we must develop or acquire and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical studies of our product candidates, obtaining marketing approvals of our product candidates, manufacturing, marketing and selling our product candidates if we obtain marketing approval, and satisfying post-marketing requirements, if any. We may never succeed in these activities and, even if we succeed in obtaining approval of and commercializing our product candidates, we may never generate revenues that are significant enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Furthermore, because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding to continue and complete the development and any commercialization of EQ101 and EQ302, and if Ono does not exercise its option, itolizumab (EQ001), and any future product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.

We expect our expenses to increase substantially during the next few years. The development of biotechnology product candidates is capital intensive. As we conduct non-clinical research and clinical development of our product candidates, we will need substantial additional funds to maintain and expand our capabilities in a variety of areas including discovery and non-clinical research, clinical development, regulatory affairs, product development, product quality assurance, and pharmacovigilance. In addition, if we obtain marketing approval of any of our product candidates, we expect to incur significant commercialization expenses for marketing, sales, manufacturing and distribution. Some of those commercialization investments may be made at-risk in advance of receiving an approval.

As of December 31, 2023, we had $40.9 million in cash, cash equivalents and short-term investments. We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2023, will enable us to fund our operations into the second half of 2025, assuming no further repurchases under our stock repurchase program. However, changing circumstances or inaccurate estimates by us may cause us to use capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our ongoing and future clinical studies of our product candidates may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expect. As of December 31, 2023, we have repurchased 298,385 shares of our common stock under the stock repurchase program for a total of approximately $0.3 million. There have been no repurchases of our common stock under the stock repurchase program since December 31, 2023 and through the date of the filing of this Annual Report on Form 10-K. The timing and amount, if any, of such further repurchases will depend on a variety of factors, including the price of our common stock, alternative investment opportunities, our cash resources, restrictions under any of our agreements, corporate and regulatory requirements and market conditions.

We do not have sufficient funds to complete the clinical development of EQ101 and, if Ono does not exercise its option, itolizumab (EQ001), through regulatory approvals for our current indications. We will need to raise substantial additional capital, and even more if we make any repurchases of shares of our common stock under our stock repurchase program, to complete the development and commercialization of each of those product candidates, which additional capital may be raised through the sale of our common stock or other securities or through the entering into of alternative strategic transactions, the terms of which may require us to divest one or more of our product candidates, such as our Asset Purchase Agreement with Ono, or cause our stockholders to incur substantial dilution.

Future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of our ongoing and future clinical studies of our product candidates, including as such activities may be adversely impacted by public health epidemics or outbreaks;
- the number and scope of indications we decide to pursue for our product development;
- non-clinical research and toxicology studies necessary to support the successful clinical development and potential approvals of our product candidates;
- formulation and device development work related to our product candidates;

- the cost, timing and outcome of regulatory review of any BLA or NDA we may submit for our product candidates;
- the costs and timing of manufacturing our product candidates and products;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- our ability to enter into partnerships or otherwise monetize our pipeline through strategic transactions on a timely basis, on terms that are favorable to us, or at all;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements, including our Asset Purchase Agreement with Ono;
- the extent to which we acquire or in-license other product candidates and technologies;
- the legal and other transactional costs associated with our business development activities;
- whether and to what extent we make repurchases of shares of our common stock under our stock repurchase program; and
- the cost associated with commercializing our product candidates if any are approved for commercial sale.

In October 2023, we entered into the 2023 ATM Facility with Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $21.95 million from time to time through Jefferies acting as our sales agent. As of the filing of this Annual Report on Form 10-K, we have not sold any shares under the 2023 ATM Facility.

Our commercial revenues, if any, are expected to be primarily derived from sales of products, which is unlikely to happen within the next 12 months, if ever. Under the Asset Purchase Agreement with Ono, we received a one-time, upfront payment of JPY 3.5 billion, or approximately $26.4 million, and are (i) entitled to receive a one-time payment of JPY 5.0 billion, or approximately $33.1 million (based on the currency exchange rate quoted by MUFG Bank, Ltd. on March 21, 2024) if Ono exercises its exclusive option to acquire our rights to itolizumab and (ii) eligible to receive up to $101.4 million upon the achievement of certain milestones. However, there is no assurance that Ono will exercise its option or that we will ever receive any milestone payments. Additionally, due to the risks associated with foreign exchange rates, if Ono exercises the Option, the one-time upfront payment of JPY 5.0 billion may result in a USD value that is significantly less than expected. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from public health epidemics or outbreaks, bank failures, the conflict between Russia and Ukraine, the conflicts in the Middle East, and monetary policy changes of federal agencies that have increased interest rates to address increasing inflationary pressures on the economy. If such disruptions persist and deepen, we could experience an inability to access additional capital. 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. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations, or enter into partnerships or otherwise monetize our pipeline through strategic transactions on terms that may not be as favorable to us as if we developed or commercialized the product candidates ourselves. Further, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation, or FDIC, took control and was appointed receiver of SVB. At the time the FDIC took control, we held assets valued at approximately $8.2 million in a sweep account with SVB. We received full access to those funds on March 13, 2023. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

Risks Related to our Business and to the Development and Regulatory Approval of our Product Candidates

We are highly dependent on the successful development of our current product candidates, EQ101, EQ302 and itolizumab (EQ001), and we may not be able to obtain regulatory or marketing approval of, or successfully commercialize, these product candidates in any of the indications for which we plan to develop them.

Our future success will depend almost entirely on our ability to successfully develop, obtain regulatory approval of and then successfully commercialize EQ101, EQ302 and itolizumab (EQ001), in any of the indications for which we are currently planning to develop them, including treatment of AA with EQ101, treatment of celiac disease or other gastrointestinal conditions with EQ302, or treatment of aGVHD and LN with itolizumab (EQ001), which may never occur. We currently generate no revenues from sales of any biopharmaceutical products, and we may never be able to develop or commercialize a marketable biopharmaceutical product.

Before we can market and sell any of our product candidates in the United States, we will need to manage research and development activities, commence and complete clinical studies, obtain necessary regulatory approvals from the FDA and build a commercial organization or enter into a marketing collaboration with a third party, among other things. We cannot assure you that we will be able to successfully complete the necessary clinical studies and/or obtain regulatory approval and develop sufficient commercial capabilities for any of our product candidates. We have not submitted a BLA or an NDA to the FDA or filed for approval with any other regulatory authority outside the United States for any product candidate. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain regulatory approval, we may never generate significant revenues from any commercial sales of any of our products. If any of our product candidates are approved and we fail to successfully commercialize them, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, prospects, financial condition and results of operations will be adversely affected.

We have and may in the future enter into partnerships or similar arrangements or otherwise monetize our pipeline through strategic transactions, which may harm our ability to realize a return, if any, on our investments and may increase our need for external funding.

We may enter into partnerships or similar arrangements or otherwise monetize our pipeline through strategic transactions for purposes of raising additional capital and allocating our available capital and other resources to developing and commercializing our other or future product candidates. For example, in December 2022 we entered into the Asset Purchase Agreement with Ono pursuant to which we granted Ono the exclusive option to acquire our rights to itolizumab (EQ001). Despite our efforts, we may be unable to enter into future partnerships or otherwise monetize our pipeline through strategic transactions with third parties on favorable terms or at all. Supporting diligence activities conducted by third parties and negotiating the financial and other terms of a strategic arrangement are long, costly and complex processes with uncertain results, and we may fail to derive any financial benefit from these activities. Any efforts toward finding a strategic partner for one or more of our product candidates may divert the time and attention of our management away from their day-to-day activities, which may adversely affect our focus on the discovery and development of our current product candidates that we intend to continue to develop and commercialize. Further, potential strategic partners may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, potentially resulting in us receiving no future milestone or royalty payments under any such arrangement. We may enter into a strategic transaction for one or more of our product candidates that prove to be more successful than the product candidates we decide to continue to develop and commercialize. As a result, our financial position and the return we realize on our research and development activities could be negatively affected, and we could be required to seek additional funding to support our operations through equity offerings, debt financings or other capital sources, which could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline. Any of the foregoing could have a material adverse effect on our competitive position, business prospects, financial condition and results of operations.

We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations with respect to our current or future product candidates, but may not be able to do so, which may cause us to alter or delay our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with biotechnology or pharmaceutical companies for the development and potential commercialization of product candidates, such as our Asset Purchase Agreement with Ono. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish other

strategic partnerships or alternative arrangements for any product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and potential parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate on the development and commercialization of product candidates other than itolizumab (EQ001), we can expect to relinquish some or all of the control over the future success of that product candidate to the partner. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the following

- the design or results of clinical studies;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our future product candidates or bring them to market and generate product revenue. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

We have limited experience in clinical development and have not successfully completed late-stage clinical studies or obtained regulatory approval for any product candidate.

We initiated our first clinical study in the first quarter of 2019, which was a Phase 1 clinical study of itolizumab (EQ001) for the treatment of aGVHD. Since then, we have initiated three additional clinical studies of itolizumab (EQ001), two of which were Phase 1 clinical studies in uncontrolled asthma and lupus/LN and one was a Phase 3 clinical study in aGVHD. The Phase 1 studies of itolizumab (EQ001) have been completed, but the Phase 3 study in aGVHD is currently ongoing. We recently completed a Phase 1 first-in-human clinical study of EQ102 in healthy volunteers in Australia, and we are currently conducting a Phase 2 clinical study of EQ101 in subjects with AA in Australia and New Zealand. We currently have two active INDs with the FDA for the use of itolizumab (EQ001) in the treatment of aGVHD and LN. Through the acquisition of Bioniz, we have INDs with the FDA for the use of EQ101 in the treatment of HTLV-I-associated myelopathy/tropical spastic paraparesis, cutaneous T cell lymphoma, or CTCL, and AA. Because of our limited interaction with the FDA, we may not learn of certain information or data that the FDA may request until future interactions. In part because of our limited infrastructure, experience conducting clinical studies as a company and regulatory interactions, we also cannot be certain that our ongoing and future clinical studies will be completed on time, if at all, that our planned clinical studies will be initiated on time, if at all, or that our planned development programs would be acceptable to the FDA.

Adverse safety and toxicology findings may emerge as we conduct non-clinical research or clinical studies. In addition, success in early clinical studies does not mean that later clinical studies will be successful, because later-stage clinical studies may be conducted in broader patient populations and involve different study designs. For example, although itolizumab

(EQ001) and ALZUMAb share the same primary monoclonal antibody sequence, they are manufactured in different cell lines and thus could be considered different biopharmaceutical products. Therefore, results seen in clinical studies of ALZUMAb conducted by Biocon may not be predictive of the results of our clinical studies of itolizumab (EQ001). Furthermore, our future clinical studies will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by the FDA. Companies frequently suffer significant setbacks in advanced clinical studies, even after earlier clinical studies have shown promising results, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical studies have nonetheless failed to obtain marketing approval of their products. In addition, only a small percentage of product candidates under development result in the submission of a BLA or NDA to the FDA and even fewer are approved for commercialization.

Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on our ability to successfully complete the above activities and any other activities required for the successful development and eventual commercialization of our product candidates. The success of our product candidates will further depend on factors such as:

- completion of our ongoing and future clinical studies and preclinical studies with favorable results, including activities that may be adversely impacted by public health epidemics or outbreaks;
- acceptance of INDs by the FDA for our future clinical studies, as applicable;
- timely and successful enrollment in, and completion of, clinical studies with favorable results;
- demonstrating safety, efficacy and acceptable risk-benefit profile of our product candidates to the satisfaction of the FDA;
- receipt of marketing approvals from the FDA;
- maintaining arrangements with our contract manufacturing organizations, or CMOs, for clinical and, if and when approved, commercial supply of EQ101 and EQ302 and with Biocon, our manufacturer of itolizumab (EQ001), for cell lines and drug product clinical supply and, if and when approved, for commercial supply of itolizumab (EQ001);
- establishing sales, marketing and distribution capabilities and launching commercial sale of our product candidates, if and when approved in one or more indications;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; and
- maintaining a continued acceptable safety profile of our products, following approval.

If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to successfully obtain marketing approval and commercialize our product candidates, which would materially harm our business.

Itolizumab (EQ001) is a monoclonal antibody that selectively targets CD6, a target for which there are no FDA-approved therapies. This makes it difficult to predict the timing and costs of clinical development for itolizumab (EQ001). We do not know whether our approach in targeting CD6 will allow us to develop any products of commercial value.

Targeting CD6 is a therapeutic approach that represents a significant component of our current research and development, and the successful development of this therapeutic approach to the diseases we are targeting for treatment plays a major factor in our future success. To date, there are no FDA-approved drugs that target CD6, and while there are a number of independent studies clinically validating CD6 as a target, other than our partner Biocon, CD6 has not traditionally been a pathway targeted by other biopharmaceutical companies. The regulatory approval process for novel product candidates such as itolizumab (EQ001) can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring itolizumab (EQ001) to market could decrease our ability to generate sufficient revenue to maintain our business.

Additionally, companion diagnostic tests may be developed for use with itolizumab (EQ001). We, or our collaborators, will be required to obtain FDA clearance or approval for these tests, as well as coverage and reimbursement separate and apart from the approval and coverage and reimbursement we seek for our itolizumab (EQ001). Our inability to collaborate with a companion diagnostics developer could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We have licensed the rights to itolizumab in the United States, Canada, Australia, and New Zealand. Any adverse developments that occur during any research, clinical, or commercial use of itolizumab by Biocon or third parties in other jurisdictions may affect our ability to obtain regulatory approval of or successfully commercialize itolizumab (EQ001) or otherwise adversely impact our business.

Biocon, its Cuban partner, CIMAB, S.A., and their licensees, over which we have no control, have the rights to develop itolizumab worldwide and commercialize itolizumab in geographies outside of the Equillium Territory (as defined below). Itolizumab is approved in India for the treatment of moderate to severe plaque psoriasis and was marketed by Biocon as ALZUMAb. Biocon was also granted restricted emergency use approval of itolizumab by the Drugs Controller General of India, or DCGI, for the treatment of cytokine release syndrome, or CRS, in COVID-19 patients with moderate to severe ARDS in India. In September 2020, the DCGI granted approval of itolizumab produced in a Chinese hamster ovary (CHO) cell line, marketed in India under the brand name ALZUMAb-L, or ALZUMAb Lyophilized, for the treatment of chronic plaque psoriasis, as well as restricted emergency use authorization for the treatment of CRS in COVID-19 patients with moderate to severe ARDS. We are also aware that ALZUMAb and ALZUMAb-L have been and ALZUMAb-L may continue to be used in India on a compassionate use basis, off label, and/or in investigator-initiated studies.

We are unaware of any currently active and ongoing clinical studies of itolizumab in Cuba. Centro de Immunologia Molecular was granted emergency use authorization of itolizumab for patients with severe COVID-19 in Cuba. We understand that itolizumab is also being studied in clinical trials in China in subjects with ARDS and dermatomyositis. Those uses of itolizumab in Cuba and China we believe are limited to itolizumab manufactured in an NS0 cell line, whereas itolizumab (EQ001) is manufactured in a CHO cell line.

The results of clinical studies with itolizumab conducted by Biocon or third parties as well as the ongoing adverse event reporting related to the clinical or commercial use of itolizumab supported by Biocon or third parties could impact our development plans and the potential commercial prospects for itolizumab (EQ001). Further, we do not control and are unable to validate study results reported by Biocon or third parties. Any errors or omissions in the data and public disclosures reported by Biocon or third parties could have a material adverse effect on our stock price and business plans.

If serious adverse events occur with patients using itolizumab as an approved therapy or during any clinical studies, exploratory studies, or other clinical uses of itolizumab conducted or supported by Biocon or third parties, regulatory authorities, including the FDA, may delay, limit or deny approval of itolizumab (EQ001), suspend our clinical development of itolizumab (EQ001), or require us to conduct additional clinical studies as a condition of marketing approval, which would increase our costs and adversely impact our business. If we receive regulatory approval of itolizumab (EQ001) and a new and serious safety issue is identified in connection with the commercial use of ALZUMAb-L or in clinical studies, exploratory studies, or other clinical uses of itolizumab conducted or supported by Biocon or third parties, regulatory authorities may withdraw their approval of the product or otherwise restrict our ability to market and sell itolizumab. In addition, treating physicians may be less willing to administer our product due to concerns over such adverse events, which would limit our ability to commercialize itolizumab (EQ001) and could potentially adversely impact our ability to conduct clinical development of itolizumab (EQ001).

If we fail to develop or acquire other product candidates or products, our business and prospects would be limited.

One element of our strategy is to expand our pipeline by acquiring a portfolio of other product candidates through business or product candidate acquisitions such as our acquisition of Bioniz. The success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire product candidates for therapeutic indications that complement or augment our current pipeline, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire suitable product candidates from third parties or acquire businesses at valuations and on other terms acceptable to us, or if we are unable to raise capital required to acquire businesses or new product candidates, our business and prospects will be limited

and may require us to divest one or more of our product candidates to enable us to acquire businesses or new product candidates or progress the development of our other product candidates.

Moreover, any product candidate we acquire may require additional, time-consuming development or regulatory efforts prior to commercial sale or prior to expansion into other indications, including preclinical studies if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical drug development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop our product candidates, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates to follow our existing product candidates or be able to acquire other product candidates to expand our existing portfolio, and our business and prospects would be harmed.

Potential natural disasters, some possibly related to the increasing effects of climate change, could damage, destroy or disrupt clinical study sites, our office spaces, laboratories, and/or warehouses, which could have a significant negative impact on our operations.

We are vulnerable to the increasing impact of climate change and other natural disasters. Volatile changes in weather conditions, including extreme heat or cold, could increase the risk of wildfires, floods, blizzards, hurricanes and other weather-related disasters. Such extreme weather events, or other natural disasters such as earthquakes, can cause power outages and network disruptions that may result in disruption to operations and may impact our ability to continue or complete our clinical studies, which will negatively impact our operations and delay our plans to commercialize our product candidates. They could also cause significant damage to or destruction of our clinical study sites resulting in temporary or long-term closures of these facilities. Such disasters could also result in loss or damage to office buildings, laboratories, employee and/or patient homes, employees and/or patients relocating to other parts of the country or being unwilling to travel to the clinical study site locations, and the inability to recruit key employees and/or enroll patients. This could result in adverse impacts to the available workforce and/or patient samples, damage to or destruction of materials and/or data, or the inability to conduct clinical studies and deliver new data.

We have licensed itolizumab from Biocon pursuant to an exclusive license agreement, which license is conditioned upon us meeting certain diligence obligations with respect to the development, regulatory approval and commercialization of itolizumab, and making significant milestone payments in connection with regulatory approval and commercial milestones as well as royalty payments.

We are party to an exclusive license agreement with Biocon, pursuant to which we initially acquired an exclusive license to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit itolizumab and any pharmaceutical composition or preparation containing or comprising itolizumab in the United States and Canada and which was later amended to grant us the same exclusive license in Australia and New Zealand as well, or, collectively, the Equillium Territory. We are obligated, under this agreement, to achieve certain development milestones within specified timeframes in order to retain all of the licensed rights. Certain of such milestones are largely outside of our control. We are also obligated to use commercially reasonable efforts to develop and seek regulatory approval of, and if regulatory approval is obtained, to commercialize, itolizumab in the Equillium Territory and to secure funding for the development of itolizumab in two or more indications. Further, we are obligated to make certain cash milestone payments to Biocon upon completion of certain regulatory approval and commercial milestones and are required to pay royalties to Biocon on net sales of itolizumab, if approved. Though we believe that the royalty rates and milestone payments are reasonable in light of our business plan, we will require large amounts of capital to satisfy these obligations. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical studies, curtail our operations, scale back our commercialization and marketing efforts or seek funds to meet these obligations on terms unfavorable to us. In addition, if we are unable to make any payment when due or, if we fail to achieve the development milestones within the timeframes required by the license agreement, or to satisfy our general diligence obligation to use commercially reasonable efforts to develop, register and commercialize itolizumab and to secure funding for the development of itolizumab in two or more indications, Biocon may have the right to limit the scope of our license or terminate the agreement and all of our rights to develop and commercialize itolizumab.

We are and may become further dependent on Ono for funding the clinical development and commercialization of itolizumab (EQ001). If Ono terminates our Asset Purchase Agreement, does not exercise its option, or does not achieve

the milestones specified in the Asset Purchase Agreement, our business and financial condition would be adversely impacted.

In December 2022, we entered into the Asset Purchase Agreement with Ono pursuant to which we granted Ono the exclusive option to acquire our rights to itolizumab (EQ001), which option expires three months following the delivery of topline data from the EQUALISE clinical study in LN and interim data from the EQUATOR Phase 3 clinical study in aGVHD. During the option period, we are responsible for conducting all research and development of itolizumab (EQ001), which is funded by Ono on a quarterly basis commencing July 1, 2022. If Ono fails to provide such funding, our financial condition and ability to conduct continued research and development of itolizumab (EQ001) would be adversely affected.

In the event that Ono exercises its option to acquire our rights to itolizumab (EQ001), we would no longer control the clinical development and potential commercialization of itolizumab (EQ001). Per the Asset Purchase Agreement and depending on Ono's election, we may conduct and be compensated for certain activities on Ono's behalf, but we would not control any itolizumab (EQ001) activities. Ono would be responsible for filing future applications with the FDA or other regulatory authorities for approval of itolizumab (EQ001) and will be the owner of any marketing approvals of itolizumab (EQ001) issued by the FDA or other regulatory authorities. If the FDA or other regulatory authorities approve itolizumab (EQ001), Ono would also be responsible for the launch, marketing and sale of the resulting product. However, we cannot control whether Ono will devote sufficient attention and resources to the clinical development of itolizumab (EQ001) or will proceed in an expeditious manner. Even if the FDA or other regulatory agencies approve itolizumab (EQ001), Ono may elect not to proceed with the commercialization of the resulting product in one or more countries. If the development of itolizumab (EQ001) does not progress for these or any other reasons, we would be prevented from obtaining further revenues, including certain development and commercialization milestones, from itolizumab (EQ001) and from otherwise realizing the benefit of such transaction, which could harm our business.

The development and commercialization of biopharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals of our product candidates in any of the indications for which we plan to develop them, or any future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to our current product candidates, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of a new therapeutic product in the United States requires the submission of an NDA or a BLA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA for that product. An NDA or BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. Similar submissions are required for approval by the relevant regulatory authority in other territories outside the United States before a therapeutic product can be marketed.

FDA and other applicable regulatory approval is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. Regulatory authorities, like the FDA, also have substantial discretion in the approval process. The number and types of preclinical studies and clinical studies that will be required for approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical studies, failure can occur at any stage. The results of preclinical and early clinical studies of our product candidates may not be predictive of the results of our later-stage clinical studies.

Clinical study failure may result from a multitude of factors including flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical studies can occur at any stage. Companies in the biopharmaceutical industry frequently suffer setbacks in the advancement of clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical studies or preclinical studies. In addition, data obtained from clinical studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA and other applicable regulatory authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem our product candidate to be adequately safe and effective;

- may not agree that the data collected from clinical studies are acceptable or sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical studies;
- may determine that adverse events experienced by participants in our clinical studies represents an unacceptable level of risk;
- may determine that population studied in the clinical study may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from studies, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes or facilities associated with our product candidate;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs. We have not obtained approval of any product from the FDA or any other applicable regulatory authority. This lack of experience may impede our ability to obtain FDA or any other applicable regulatory approval in a timely manner, if at all, of our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of any of our product candidates, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical studies could result in increased costs to us, delay or limit our ability to raise capital or generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical studies of our product candidates in any distinct indication in the United States, we must submit the results of preclinical studies to the FDA along with other information, including information about their chemistry, manufacturing and controls and our proposed clinical study protocol, as part of an IND or similar regulatory filing. To date, we have only submitted INDs for clinical studies of itolizumab (EQ001) for the treatment of aGVHD, LN, and COVID-19. In addition, there are open INDs for EQ101 in HTLV-I-associated myelopathy/tropical spastic paraparesis, CTCL and AA, which were originally filed by Bioniz prior to our acquisition of the EQ101 asset.

Before obtaining marketing approval from the FDA or from any other applicable regulatory authority outside of the United States for the sale of any of our product candidates in any indication, we must conduct extensive clinical studies to demonstrate the safety and efficacy of those product candidates. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our partner, Biocon, as well as contract research organizations, or CROs, and other contracted parties for regulatory submissions for our product candidates. While we have or will have agreements governing these contracted parties' services, we have limited influence over their actual performance. If these parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

The FDA and other applicable regulatory authorities may require us to conduct additional preclinical studies of our existing or any future product candidates before they allow us to initiate clinical studies, which may lead to additional delays and increase the costs of our preclinical development programs. Any such delays in the commencement or completion of our ongoing, planned or future clinical studies could significantly affect our product development costs. We do not know whether our ongoing and future studies will be completed on schedule, if at all, or whether our studies will begin on time, if at all. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or other applicable regulatory authorities disagreeing as to the design or implementation of our clinical studies;

- obtaining FDA or other applicable regulatory authorizations to commence a study or reaching a consensus with the applicable FDA regulators on study design;
- any failure or delay in reaching an agreement with CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- obtaining approval from one or more Institutional Review Boards, or IRBs;
- additional nonclinical pharmacology and toxicology studies to support Phase 2 and 3 clinical studies;
- IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the study;
- changes to clinical study protocol;
- clinical sites deviating from study protocol or dropping out of a study;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical studies;
- subjects failing to enroll or remain in our study at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment, or participating in competing clinical studies;
- lack of adequate funding to continue the clinical study;
- cost of preclinical research and testing being greater than anticipated or greater than our available financial resources;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in studies of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA (or its own regulatory authorities if such facility is located outside the United States) to temporarily or permanently shut down or cease export of such materials due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, changes in export restrictions and controls, or infections or cross-contaminations during the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- impacts and risks associated with global health epidemics or outbreaks;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical studies, not performing our clinical studies on our anticipated schedule or consistent with the clinical study protocol, Good Clinical Practices, or GCP, or other regulatory requirements;
- data collection or analysis in an untimely or inaccurate manner or improper disclosure of data prematurely or otherwise in violation of a clinical study protocol by us or our contractors; or
- our contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical study is modified, suspended or terminated by us, by the IRBs of the institutions in which such studies are being conducted, by a Data Safety Monitoring Board for such study or by the FDA or by other regulatory agencies or health authorities that have jurisdiction in countries in which the study is being conducted. Such authorities may impose such a suspension or termination, or a modification to our study protocol, due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols, inspection of the clinical study operations or study site by the FDA or other regulatory agencies resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study. In addition,

changes in regulatory requirements and policies may occur, and we may need to amend clinical study protocols to comply with these changes. Amendments may require us to resubmit our clinical study protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical study.

Certain of our scientific advisors or consultants who receive compensation from us are likely to be investigators for our future clinical studies. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory agencies. The FDA or other regulatory agencies may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the clinical study. The FDA or other applicable regulatory agency may therefore question the integrity of the data generated at the applicable clinical study site and the utility of the clinical study itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory agencies and may ultimately lead to the denial of marketing approval of our product candidates in one or more indications. If we experience delays in the completion of, or termination of, any clinical study of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical studies will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues from product sales which may harm our business, financial condition, results of operations and prospects significantly.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical studies, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to continue our ongoing or initiate our future clinical studies of our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these studies as required by the FDA or other applicable regulatory authorities. Multiple factors could contribute to such challenges of enrolling our clinical studies, including impacts related to public health epidemics or outbreaks, which have previously adversely impacted enrollment in our clinical studies. In addition, some of our competitors may have ongoing clinical studies for product candidates that would treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical studies may instead enroll in clinical studies of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical study investigators of appropriate competencies and experience;
- invasive procedures required to obtain evidence of the product candidate's performance during the clinical study;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the study in question;
- the size of the patient population required for analysis of the study's primary endpoints;
- perceived risks and benefits;
- efforts to facilitate timely enrollment in clinical studies;
- reluctance of physicians to encourage patient participation in clinical studies;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- proximity and availability of clinical study sites for prospective patients; and
- impacts and risks associated with global health epidemics or outbreaks.

Our inability to enroll and retain a sufficient number of patients for our clinical studies would result in significant delays or may require us to abandon one or more clinical studies altogether. Enrollment delays in our clinical studies may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical studies, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates in our ongoing and future clinical studies as well as in clinical studies, investigator-initiated studies, and commercial usage in jurisdictions where itolizumab is available commercially.

EQ101 has been well-tolerated with no dose limiting toxicities or infusion reactions reported in subjects that have been dosed in prior studies completed by Bioniz, including healthy volunteers, subjects with large granular lymphocyte leukemia and CTCL. Our Phase 2 clinical study of EQ101 in subjects with AA is currently ongoing.

Based on our current limited clinical experience with itolizumab (EQ001), expected adverse events include lymphopenia, injection site reactions, infusion-/injection-related reactions (including fever and headache), and other systemic hypersensitivity reactions including rash, urticaria, erythema, and pruritus.

The most common adverse drug reactions that have been identified from the itolizumab (EQ001) clinical programs were injection site reactions (designated an identified risk) with SC administration and lymphopenia (designated an important identified risk). Additionally, infection has been designated as an important potential risk. Lymphopenia events were common treatment emergent adverse events reported across itolizumab (EQ001) studies. A decrease in lymphocyte count is a known pharmacodynamic marker of itolizumab (EQ001). These events were generally transient following the first dose, did not decline with continued dosing, and resolved when itolizumab (EQ001) treatment was withdrawn. Further, the declines in lymphocyte count were not associated with infection or other clinical sequelae.

Biocon may also continue to support the use of ALZUMAb-L in their own sponsored clinical studies, off-label use, investigator-initiated studies, or third party-sponsored studies over which we have no control. For example, Biocon is studying itolizumab in ulcerative colitis as part of a Phase 2 clinical study being conducted in India, which Equillium is collaborating and co-funding. Given such ongoing usage of itolizumab by Biocon or third parties, there is a risk that adverse events may impact our ability to conduct clinical development and successfully commercialize itolizumab (EQ001). Further, there is a risk that any such adverse events are not properly reported, which may also adversely impact our business.

Although itolizumab (EQ001) and ALZUMAb share the same primary monoclonal antibody sequence, they are manufactured in different cell lines and thus could be considered different biopharmaceutical products. Therefore, clinical results seen with ALZUMAb may have no bearing on results, including adverse events, that may be seen with itolizumab (EQ001). Through the date of the filing of this Annual Report on Form 10-K, we are not aware of any meaningful change in the benefit-to-risk profile of itolizumab.

Results of our clinical studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical studies by us, the FDA or other applicable regulatory authorities for a number of reasons. Additionally, a material percentage of patients in our aGVHD clinical studies may die from this disease, possibly as a result of itolizumab (EQ001), which could impact development of itolizumab (EQ001). If we elect or are required to delay, suspend or terminate any clinical study, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Serious adverse events observed in clinical studies could hinder or prevent market acceptance of our product candidates. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if any of our product candidates are associated with undesirable side effects in clinical studies or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our product candidates, if approved. We may also be required to modify our study plans based on findings in our clinical studies. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our product candidates in larger, longer and more extensive clinical studies, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier studies, as well as conditions that did not occur or went undetected in previous studies, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by that approved product or any related products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the approved product;
- we may be required to recall a product or change the way the approved product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, “Dear Healthcare Provider” letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- the approved product could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any of our product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Interim, topline or preliminary data from our clinical studies 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 preliminary or topline data from our preclinical and clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same preclinical and clinical studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our studies. Interim data from studies 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 preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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 company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical study 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 biopharmaceutical product, biopharmaceutical product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval of, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

In the past, we have conducted clinical studies of itolizumab (EQ001) outside of the United States, and we are and may in the future continue to use sites outside of the United States for clinical studies of EQ101 and itolizumab (EQ001), including our Phase 3 pivotal clinical study of itolizumab (EQ001) in aGVHD, as well as possibly for clinical studies of

any other product candidates. The FDA may not accept data from such studies, in which case our development plans will be delayed, which could materially harm our business.

In the fourth quarter of 2017, Biocon completed a Phase 1 clinical study of itolizumab (EQ001) in healthy subjects in Australia to assess the safety and tolerability of the SC version of itolizumab (EQ001). The study also included a separate stage to compare the pharmacokinetics of the IV administration of itolizumab (EQ001) to ALZUMAb and determine the absolute bioavailability of SC itolizumab (EQ001), but this stage was terminated early due to the occurrence of an initial decrease in lymphocyte counts and transient lymphopenia. We submitted this data to the FDA as part of our IND submissions for the conduct of clinical studies for the treatment of aGVHD, LN and COVID-19. However, it is possible that the FDA will not authorize us to proceed with clinical studies in connection with any future IND submissions in other indications that have different patient populations and we may be required to conduct additional Phase 1 clinical studies, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

We have utilized sites in Australia and New Zealand for a Phase 1b clinical study of itolizumab (EQ001) in uncontrolled moderate to severe asthma, and we have utilized sites in India for a Phase 1b clinical study of itolizumab (EQ001) in lupus and LN. Also, we are utilizing sites from a variety of countries outside of the United States in our pivotal Phase 3 clinical study of itolizumab (EQ001) in aGVHD, including sites in Europe, Asia and elsewhere. Our Phase 2 clinical study of EQ101 in subjects with AA is being conducted in Australia and New Zealand. Although the FDA may accept data from clinical studies conducted entirely outside the United States and not under an IND, acceptance of such clinical study data is generally subject to certain conditions. For example, the FDA requires the clinical study to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical studies through an onsite inspection if it deems such inspection necessary. In addition, when clinical studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical study was inadequate, which would likely require us to conduct additional clinical studies. Conducting clinical studies outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to test our product candidates in the future. We may expend our limited resources to pursue a particular indication for a product candidate and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Our translational biology program may initially show promise in identifying additional indications for which our product candidates may have therapeutic benefit, yet this may fail to yield additional clinical development opportunities for our product candidates for a number of reasons, including, our product candidates may, on further study, be shown to have harmful side effects, limited to no efficacy or other characteristics that indicate that it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. Research programs to identify additional indications for our product candidates require substantial technical, financial and human resources.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our development efforts on the potential treatment of certain, limited indications. As a result, we may forego or delay pursuit of opportunities with other indications or for any future product candidates, or divest product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending toward developing our product candidates for specific indications may not yield any approved or commercially viable products. If we do not accurately evaluate the commercial potential or target market for our product candidates, we may pursue indications that are less attractive and may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Even if we receive regulatory approval of any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of our

product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals of our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical studies, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves any product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for the product will be subject to extensive and ongoing regulatory requirements, which can be costly and time consuming. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs, for any clinical studies that we conduct post-approval. We must incur significant expenses and spend time and effort to ensure compliance with these complex regulations. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, undesirable side effects caused by the product, problems encountered by our contracted manufacturers or manufacturing processes, or failure to comply with regulatory requirements, either before or after product approval, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- requirements to include additional warnings on the label;
- requirements to create a medication guide outlining the risks to patients;
- withdrawal of the product from the market;
- voluntary or mandatory product recalls;
- requirements to change the way the product is administered or for us to conduct additional clinical studies;
- fines, warning letters or holds on clinical studies;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- harm to our reputation.

Additionally, if any product candidate receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the therapy outweigh its risks, which may include, among other things, a medication guide outlining the risks for distribution to patients and a communication plan to health care practitioners. Any of these events could prevent us from achieving or maintaining market acceptance of the product or the particular product candidate at issue and could significantly harm our business, prospects, financial condition and results of operations.

In addition, if we have any product candidate approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about biopharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain

regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Even if our product candidates receive marketing approval in any indication, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.

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

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer the approved product for sale at competitive prices;
- 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;
- the strength of marketing and distribution support;
- potential product liability claims;
- the timing of market introduction as well as competitive biopharmaceutical products;
- the effectiveness of our or any of our potential future sales and marketing strategies;
- unfavorable publicity;
- sufficient third-party payor coverage and adequate reimbursement;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with contracted third parties to market and sell any of our approved products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute it. We may have to seek collaborators or invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that any of our product candidates will be approved, if at all. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on contracted parties for these functions than if we were to market, sell and distribute our products ourselves. We likely will have limited control over such contracted parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by any approved product candidates; and
- our direct sales and marketing efforts may not be successful.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.

The development and commercialization of new products is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop drugs and biologics for the treatment of immuno-inflammatory diseases. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop, or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval of their products more rapidly than we may obtain approval of ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We are aware that other products addressing the same indications as EQ101, EQ302 and itolizumab (EQ001) are in development, and some have been approved. For the treatment of AA, Eli Lilly and Company has received FDA approval of Olumiant, and Pfizer Inc. has recently received FDA approval of Litfulo. Other private and public companies involved in AA drug development include Arcutis Biotherapeutics, Inc., ASLAN Pharmaceuticals Limited, Bristol-Myers Squibb Company, Concert Pharmaceuticals, Inc. (acquired by Sun Pharmaceutical Industries Ltd.), Forte Biosciences, Inc., Horizon Therapeutics plc (acquired by Amgen Inc.), Inmagene Biopharmaceuticals Co. Ltd., Legacy Healthcare, Nektar Therapeutics, Ornovi Inc., Pfizer Inc., Q32 Bio Inc., Reistone Biopharma, Zelgen Biopharmaceuticals Co., Ltd., and Zura Bio Limited. There are no approved products for celiac disease. Private and public companies with development programs targeting celiac disease include Amgen Inc., Anokion SA, Calypso Biotech BV (acquired by Novartis AG), Chugai Pharmaceutical Co., Ltd., IGY Immune Technologies & Life Sciences Inc., Immunic, Inc., ImmunogenX, Inc., Protagonist Therapeutics, Inc., Takeda Pharmaceuticals, Teva Pharmaceuticals, Topas Therapeutics GmbH, and Zedira GmbH. There are no FDA-approved therapies indicated as a first-line treatment of aGVHD. Second-line therapy consists of off-label immunosuppressives for which the therapeutic benefit has not been established, and Incyte Corporation’s ruxolitinib which was approved for the treatment of steroid refractory aGVHD in 2019. Other private and public companies with development programs in first-line and steroid refractory aGVHD, include AltruBio, Inc., ASC Therapeutics, CSL Behring LLC, Cynata Therapeutics Limited, ElsaLys Biotech, Evive Biotech (subsidiary of Yifan Pharmaceutical Co., Ltd.), Humanigen, Inc., Maat Pharma SA, Medac GmbH, Mesoblast Limited, Shenzhen Xbiome Biotech, Co., Ltd., TR1X Inc., VectivBio Holding AG (acquired by Ironwood Pharmaceuticals, Inc.), ViGenCell Inc., and Zelgen Biopharmaceuticals Co., Ltd. There are currently two approved therapies for the treatment of LN: GlaxoSmithKline’s Benlysta, approved in 2020, and Aurinia Pharmaceuticals’ Lupkynis, approved in January 2021. Other private and public companies involved in LN drug development include AstraZeneca plc, Corestem Co., Ltd., CSL Behring LLC, Genentech Inc., Jansen Pharmaceutical Companies of Johnson & Johnson, Kezar Life Sciences, Inc., Nkarta, Inc., Novartis AG, Omeros Corporation and Vera Therapeutics, Inc.

Many of our competitors, such as large pharmaceutical and biotechnology companies like Pfizer Inc. and Eli Lilly and Company, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we have. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, these larger companies may be able to use their greater market power to obtain more favorable distribution and sales-related agreements with third parties, which could give them a competitive advantage over us.

Further, as more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical studies for product candidates in those classes will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenues and financial condition would be materially and adversely affected.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and subject enrollment for clinical studies, as well as in acquiring technologies complementary to, or necessary for, EQ101, EQ302, itolizumab (EQ001) or any future programs.

The key competitive factors affecting the success of any of our product candidates are likely to be their efficacy, safety, convenience and availability of reimbursement. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

Our current product candidates and any future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical studies to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If market opportunities for our product candidates are smaller than we believe they are, our potential revenue may be adversely affected and our business may suffer.

We only have the rights to itolizumab (EQ001) for the Equillium Territory, and we are focused on the development of itolizumab (EQ001) for autoimmune and inflammatory diseases, with current plans to develop it for the treatment of patients with aGVHD and LN. We have global rights to EQ101 and EQ302 and currently have plans to develop those product candidates for AA and gastrointestinal diseases such as celiac disease, respectively. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates and may prove to be incorrect. If any of our estimates are inaccurate, the market opportunities for our product candidates could be significantly diminished and have an adverse material impact on our business.

We may not ultimately realize the potential benefits of orphan drug designation for EQ101 or itolizumab (EQ001).

EQ101 has been granted orphan drug designation by the FDA and the European Medicines Agency for CTCL, and itolizumab (EQ001) has been granted orphan drug designations by the FDA for both the prevention and treatment of aGVHD. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years (with certain exceptions). However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process. Even if we are awarded marketing exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to assure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully

enforce any remaining patents covering our eligible product candidates, we could be subject to biosimilar competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as EQ101 or itolizumab (EQ001), we may face increased competition and lose market share regardless of orphan drug exclusivity.

Fast-track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We have received fast-track designation for itolizumab (EQ001) for the treatment of aGVHD and LN. If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA fast-track designation. Even with fast-track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast-track designation if it believes that the designation is no longer supported by data from our clinical development program.

Even if we receive marketing approval, we may not be able to successfully commercialize any of our approved products due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell any of our approved products profitably.

Obtaining coverage and adequate reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our approved products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting pharmaceutical prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Similarly, because our product candidates are physician-administered injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may be reimbursed for providing the treatment or procedure in which our product is used. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that

we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a third-party payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Additionally, if we or our collaborators develop companion diagnostic tests for use with our product candidates, such tests will be subject to the coverage and reimbursement process separate and apart from the coverage and reimbursement we seek for our product candidates.

We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products.

Risks Related to Manufacturing and Our Reliance on Third Parties

The manufacture of pharmaceutical products, especially biologics, is complex and we may encounter difficulties in production, distribution and delivery of our product candidates. If CMOs, including Biocon, our exclusive CMO for itolizumab (EQ001), encounter such difficulties, our ability to provide supply of our product candidates for clinical studies, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, if approved, could be delayed or stopped.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We are completely dependent on third-party CMOs to fulfill our clinical and commercial supply of our product candidates. However, the process of manufacturing pharmaceutical products, especially biologics, is complex, highly-regulated and subject to multiple risks. Such manufacturing is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical studies, result in higher costs of drug product and adversely harm our business. In addition, if the facilities of our manufacturer are located outside of the United States, as is the case currently for itolizumab (EQ001), the production, distribution and delivery of pharmaceutical products are also subject to the laws and regulations of the country. Any changes in the laws and regulations of another country, or disruptions in production or the supply chain related to geopolitical issues or health pandemics, could delay clinical studies, result in higher costs of drug product and adversely harm our business. Moreover, if the FDA determines that our manufacturer is not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical studies or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability and delivery of raw materials. Even if we obtain regulatory approval of our product candidates or any future product candidates, there is no assurance that our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. Further, our contracted manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health epidemics. If our manufacturers are unable to

produce sufficient quantities for clinical studies or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Scaling up pharmaceutical manufacturing processes, especially biological processes and peptide synthesis, is a difficult and uncertain task, and our CMOs may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely deliver our supplies of EQ101, EQ302, itolizumab (EQ001) or other future product candidates (including other biologics) or meet product demand.

In May 2017, we entered into an exclusive clinical supply agreement with Biocon and have agreed to enter into an exclusive commercial supply agreement with Biocon in the future. Biocon manufactures itolizumab (EQ001) at its FDA regulated facility in Bangalore, India. Our dependence on Biocon subjects us to further risks and uncertainties related to our ability to fulfill our clinical and commercial supply of itolizumab (EQ001). For example, in March 2020, due to the spread of the coronavirus, the Indian government restricted the export of 26 active pharmaceutical ingredients and the medicines made from them. These export restrictions are indefinite and may be modified or expanded. If the export restrictions are expanded to include itolizumab (EQ001), our supply of itolizumab (EQ001) may be disrupted, delayed or stopped indefinitely and our ability to continue development of itolizumab (EQ001), including our ongoing clinical studies, may be significantly impacted and may result in higher costs of drug product and adversely harm our business. If Biocon is unable to meet our manufacturing requirements (due to export restrictions or otherwise), it has the discretion to outsource manufacturing to a third party and the joint steering committee may determine to shift manufacturing to a third party. However, transfer of the manufacturing of biologic products to a new contract manufacturer, whether related to itolizumab (EQ001) or any of our current or future product candidates, can be lengthy and involve significant additional costs. Even if we are able to adequately validate and scale-up the manufacturing process with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us, if at all. In addition, Biocon has certain rights to reacquire exclusive manufacturing rights for itolizumab (EQ001), even after a third party has been engaged following shortfalls by Biocon, which may make it difficult and expensive to engage any third-party manufacturer for itolizumab (EQ001) other than Biocon.

We rely, and intend to continue to rely, on CROs to conduct our clinical studies and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our preclinical testing or clinical studies ourselves. As a result, we are and will be dependent on third parties to conduct our ongoing and future preclinical studies and clinical studies of EQ101, EQ302 and itolizumab (EQ001) and any future preclinical studies and clinical studies of any other product candidates. The timing of the initiation and completion of these studies will therefore be partially controlled by such third parties and may result in delays to our development programs.

Specifically, we expect CROs, clinical investigators and consultants to play a significant role in the conduct of these studies and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical study is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. Should our CROs engage in unethical, illegal, or non-compliant activities, such behavior could adversely impact our business. Further, should we terminate our contractual relationship with a CRO for such improprieties, transitioning to a different CRO may delay, disrupt or otherwise adversely impact the progress of the clinical study. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of study sponsors, clinical study investigators and clinical study sites. If we or any of our CROs or clinical study sites fail to comply with applicable GCP requirements, the data generated in our clinical studies may be deemed unreliable, and the FDA may require us to perform additional clinical studies before approving our marketing applications. In addition, our clinical studies must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical studies, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical study investigators or other third parties on which we rely on will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or

delayed or our development activities may be suspended or terminated. If our clinical study site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical study unless we are able to transfer those subjects to another qualified clinical study site, which may be difficult or impossible. In addition, clinical study investigators for our clinical study may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA. Any such delay or rejection could prevent us from commercializing EQ101, itolizumab (EQ001) or any future product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical studies or other biopharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals of EQ101, itolizumab (EQ001) or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Our reliance on contracted parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on contracted parties to research, develop, and manufacture our product candidates, we must share trade secrets with them. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of confidentiality agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

Agreements with our advisors, employees, contractors and consultants may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements, independent development or publication of information by any of our collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights covering our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and we may not be able to compete effectively in our market.

Our success depends in significant part on our, and with respect to itolizumab (EQ001), Biocon's, ability to establish, maintain and protect patents and other intellectual property rights with respect to our proprietary technologies, research programs, and product candidates, including EQ101, EQ302 and itolizumab (EQ001), and operate without infringing the intellectual property rights of others. The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or partners 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 and future licensors, licensees or partners will fail to identify patentable aspects of our research or inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Although we enter into confidentiality agreements with parties who have access to patentable aspects of our research and development programs, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, independent contractors, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection on technology relating to our research programs. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or partners. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or

eliminated. If our licensors, licensees or partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, allowing foreign competitors a better opportunity to create, develop and market competing product candidates, or vice versa. We cannot be certain that the claims in our pending patent applications directed to our product candidates such as EQ101, EQ302 and itolizumab (EQ001), as well as technologies relating to our research programs, will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or partners' patent rights are highly uncertain. Our and our licensors', licensees' or partners' pending and future patent applications may not result in patents being issued, which protect our technology or products, in whole or in part, or their intended uses, methods of manufacture or formulations, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or partners to narrow the scope of the claims of our or our licensors', licensees' or partners' pending and future patent applications, which may limit the scope of patent protection that may be obtained. In the past, we have not always been able to obtain the full scope of patent protection we have initially sought in our patent applications, and as described above and as is typical for most biotechnology patent prosecution, we have been required to narrow or eliminate patent claims as part of the patent prosecution process. In addition, some patent applications that we or our licensors have filed have not resulted in issued patents because we or our licensors have abandoned those patent applications as changes in business and/or legal strategies dictated.

We cannot assure you that all of the potentially relevant prior art—information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention—relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application, and we may be subject to a third party pre-issuance submission of prior art to the USPTO. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate litigation or opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated, may allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or limit the duration of the patent protection of our technology and products. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Our and our licensors', licensees' or partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to our research programs and product candidates such as EQ101, EQ302 and itolizumab (EQ001). Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for EQ101, EQ302, itolizumab (EQ001) or any other product candidates that we may identify, our business may be materially harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the expiration of the patent. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, the applicable authorities, including the FDA and USPTO, in the United States, and any equivalent foreign regulatory authority, 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. If this occurs, our competitors may take advantage of our investment in development and clinical studies by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

The degree of future protection for our proprietary rights is uncertain, and we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether any of the patents we own or license will be found to ultimately be valid and enforceable;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether the patents of others will not have an adverse effect on our business;
- whether we will develop additional proprietary technologies or products that are separately patentable;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We depend on intellectual property licensed from Biocon and termination of our license could result in the loss of significant rights, which would harm our business.

We currently in-license certain intellectual property that is important to our business from Biocon and, in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. We rely to some extent on Biocon to file patent applications and to otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by Biocon have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which Biocon initiates an infringement proceeding against a third-party infringer of the intellectual property rights or defends certain of the intellectual property that is licensed to us. It is possible that our licensor's infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Furthermore, in-licensed patents may be subject to a reservation of rights by one or more third parties. Further, our existing license with Biocon imposes, and future agreements may also impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, we may be required to pay damages and our licensor may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property and our competitors or other third parties might be able to gain access to technologies and products that are identical to ours. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third

parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. Disputes may also arise between us and our licensor regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

In addition, intellectual property or technology license agreements, including our existing agreements, are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our 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. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensor fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our product candidates such as EQ101, EQ302, itolizumab (EQ001) and/or others. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

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

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include 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 products or may elect not to continue or renew development or commercialization programs based on study or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; 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.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to our therapeutic research programs or necessary for the commercialization of our product candidates such as EQ101, EQ302, itolizumab (EQ001) and/or others in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties, and 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 products and/or product candidates that we may identify. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware, potentially

relating to our research programs and product candidates such as EQ101, EQ302, itolizumab (EQ001) and others, or their intended uses. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, which include EQ101, EQ302, itolizumab (EQ001) and others, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell EQ101, EQ302 and itolizumab (EQ001), and other potential future product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property that relate to our current and future product candidates, including EQ101, EQ302, itolizumab (EQ001) and others, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, we or our licensor may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we or our licensor assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and the outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent that we own or have licensed is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. For example, an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical studies, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring EQ101, EQ302, itolizumab (EQ001) or other product candidates that we may identify to market. Any of these occurrences could adversely affect our competitive business position, results of operations, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent relating to our research programs and product candidates, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. We could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, including EQ101, EQ302 or itolizumab (EQ001), if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

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

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, 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. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, the new unitary patent system that came into effect in June 2023 would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is no 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. 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.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, 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 fail to maintain the patents and patent applications covering our research programs and product candidates such as EQ101, EQ302, itolizumab (EQ001) and others as well as their respective methods of use, manufacture and formulations thereof, our competitive position would be adversely affected, as, for example, competitors might be able to enter the market earlier than would otherwise have been the case.

We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical studies or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Moreover, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though

our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensor may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an owner, co-owner, inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. In addition, while it is our policy to require our employees, consultants, advisors, contractors and other third parties who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we or our licensors may be unsuccessful in executing such agreements with each party who, in fact, conceives or develops intellectual property rights that we regard as our own. The assignment of intellectual property rights may not be self-executing or sufficient in scope, or the assignment agreements may be breached. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us or our licensors may be ineffective in perfecting ownership of inventions developed by that individual. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patent rights are of limited duration. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Further, recent judicial decisions in the United States raised questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

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.

We currently have two U.S. trademark registrations for EQUILLIUM respectively covering Classes 5 and 42, and one Canadian trademark registration for EQUILLIUM covering both Classes 5 and 42. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Employees, Managing Our Growth and Other Legal Matters

We are highly dependent on the services of our key personnel.

We are highly dependent on the services of our key personnel, Bruce D. Steel, who serves as our President and Chief Executive Officer and Stephen Connelly, Ph.D., who serves as our Chief Scientific Officer. Although we have entered into agreements with them regarding their employment, they are not for a specific term and each of them may terminate their employment with us at any time, though we are not aware of any present intention of any of these individuals to leave us.

We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2023, we had 44 full-time employees. As we advance the clinical development of EQ101 and itolizumab (EQ001), and potentially other product candidates, we expect to experience significant growth in the number of our

employees and the scope of our operations across a variety of areas including non-clinical research, clinical development, quality, regulatory affairs, pharmacovigilance, manufacturing and supply chain, as well as general and administrative functions. If EQ101, EQ302, itolizumab (EQ001), or any future product candidates receive marketing approval, we would expect to add employees in sales, marketing and distribution. To manage our anticipated future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- identify and lease additional facilities;
- manage our development efforts effectively, including the initiation and conduct of clinical studies for EQ101, EQ302, itolizumab (EQ001) and any future product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain CROs, CMOs, other contract service providers, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our ongoing and future clinical studies and the manufacture of EQ101, EQ302, itolizumab (EQ001) and any future product candidates. We cannot assure you that the services of such contract service providers, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by leasing additional facilities, hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We conduct our operations primarily in the Greater San Diego Area region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated.

Third-party expectations relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

In recent years, there has been an increased focus from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Third-party providers of ESG ratings and reports on companies have increased in number, resulting in varied and, in some cases, inconsistent standards. Topics taken into account in such assessments include, among others, the company's efforts and impacts with respect to climate change and human rights, ethics and compliance with the law, and the role of the company's board of directors in supervising various sustainability issues.

Some investors may use third-party ESG ratings and reports to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ESG practices are inadequate. The criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy new criteria or do not meet the criteria of a specific third-party provider, some investors may conclude that our policies with respect to ESG are inadequate and choose not to invest in us.

If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our desirability as an investment or business partner could be negatively impacted. Similarly, our failure or perceived failure to adequately pursue or fulfill our goals and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could expose us to additional regulatory, social or other scrutiny of us, the imposition of unexpected costs, or damage to our reputation, which in turn could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline.

Our employees, clinical study investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical study investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, 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 comply with these laws or regulations. 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, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If our information technology systems, or those of our CROs or other third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, data we collect about trial participants in connection with clinical studies, sensitive third-party data, business plans, transactions, financial information, intellectual property, and trade secrets (collectively, sensitive information).

As a result, we and the third parties upon which we rely face a variety of evolving threats that could cause security incidents. Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-sate actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, human capital management, document management, preclinical research, clinical studies including data management, biostatistics, and safety reporting, manufacturing of drug product, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption, that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products and services.

We may expend significant resources or modify our business activities (including our clinical study activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures, or industry-standard or reasonable security measures designed to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; ; diversion of management attention; interruptions in our operations (including the delay of development and commercialization of our product candidates); financial loss; and other similar harms. Security incidents and attendant consequences that we or our third party providers could experience may prevent or cause customers to stop using our products and services, deter new customers from using our products and services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

Our data processing activities, including acquisition and processing of information from study participants, subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of t
he Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical study data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to penalties, including criminal penalties, if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, collectively the CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in

several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, may also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, several states and localities, as well as foreign jurisdictions, have enacted statutes banning or restricting the collection of biometric information. We use identity verification technologies that may subject us to biometric privacy laws. For example, the Illinois Biometric Information Privacy Act, or BIPA, regulates the collection, use, safeguarding, and storage of biometric information. BIPA provides for substantial penalties and statutory damages and has generated significant class action activity, and the cost of litigating and settling any claims that we have violated BIPA or similar laws could be significant. In addition to litigation, regulators, such as the Federal Trade Commission (FTC), have indicated that use of biometric technologies (including facial recognition technologies) may be subject to additional scrutiny.

Our employees and personnel may use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, India's Information Technology Act and supplementary rules, and Australia's Privacy Act, impose strict requirements for processing personal data.

For example, under GDPR, companies may face temporary or definitive bans on data processing, and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient,

lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have an adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical studies); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited and as a result, our future tax liability may increase.

As of December 31, 2023, we had aggregate U.S. federal net operating loss, or NOL, carryforwards of approximately $76.9 million. Under current U.S. federal income tax law, U.S. federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such U.S. federal NOLs is generally limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the current U.S. federal income tax law.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage-point cumulative 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 tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We determined that we experienced one or more ownership changes prior to June 30, 2023. However, the ownership changes prior to June 30, 2023, are not expected to significantly impact the Company's ability to utilize its NOLs and other tax attributes. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which may be outside of our control. As a result, our ability to use our pre-ownership change NOL carryforwards to offset U.S. federal taxable income in the future (if we earned net taxable income) and any other pre-ownership change tax attributes may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We conduct significant operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations will suffer.

In January 2019, we formed a wholly-owned Australian subsidiary, Equillium Australia Pty Ltd, to initially conduct the clinical development of itolizumab (EQ001) for the treatment of uncontrolled asthma in Australia and New Zealand. That subsidiary conducted our Phase 1 study of EQ102, which has been completed, and is also conducting our current clinical study of EQ101 and may conduct further clinical studies in the future. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop or commercialize our product candidates in Australia and New Zealand, including conducting clinical studies. Furthermore, we have no assurance that the results of any clinical studies that we conduct for our product

candidates in Australia and New Zealand will be accepted by the FDA or other foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit. If we lose our ability to operate Equillium Australia Pty Ltd in Australia, are ineligible or unable to receive the research and development tax credit, receive a refund that is materially less than our expectations, or if the Australian government significantly reduces or eliminates the tax credit, or if upon the results of an audit the Australian Taxation Office rules that prior claims were invalid and requires repayment of previous refund amounts, our financial forecasts could be incorrect and our business and results of operations would be adversely affected.

If we fail to comply with U.S. export control and economic sanctions, our business, financial condition and prospects may be materially and adversely affected.

Our business and our products are subject to U.S. export control laws and regulations, including the U.S. Export Administration Regulations and economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, or OFAC. Our company must comply with these laws and regulations. The antibody sequence for itolizumab (EQ001) is derived from Cuban-origin intellectual property and thus we believe this to be a pharmaceutical of Cuban origin, which would make the import, development and commercialization of itolizumab (EQ001) subject to these laws, sanctions and regulations. We currently rely on a general license issued by OFAC under the Cuban Assets Control Regulations, or CACR, relating to Cuban-origin pharmaceuticals to import and conduct clinical studies relating to itolizumab (EQ001). In the absence of the OFAC general license, all of our development and potential commercialization activities for itolizumab (EQ001) would be prohibited under the CACR, and we would be required to request a specific license from OFAC authorizing such activities, which OFAC could deny.

We submitted to OFAC, and subsequently amended and supplemented, a request for interpretive guidance confirming the applicability of the general license to itolizumab (EQ001), or in its absence, a specific license authorization from OFAC authorizing activities relating to the commercialization of itolizumab (EQ001), or the Submission. We simultaneously requested that OFAC treat the Submission as a voluntary disclosure if OFAC concluded that our determination that the general license applies to itolizumab (EQ001) was in error.

In November 2019, OFAC notified us that after careful consideration, which included consultation with the FDA, OFAC determined that itolizumab (EQ001) falls within the definition of "Cuban-origin pharmaceutical" and, as such, the general licenses at section 515.547(b) and (c) of the CACR authorize the conduct of clinical studies for itolizumab (EQ001) for the purpose of seeking approval of the drug from the FDA. Thus, no further authorization is required from OFAC at this time for our ongoing and future clinical studies of itolizumab (EQ001).

Even though OFAC has concluded that the general license for Cuban-origin pharmaceuticals applies to itolizumab (EQ001), there can be no assurance that the general license will not be revoked or modified by OFAC in the future, or that we will remain in compliance with the general license or other export laws and regulations. If OFAC revokes or modifies the general license, or otherwise determines that the general license does not apply to itolizumab (EQ001), and OFAC then denies our request for a specific license or delays issuance of a specific license, we will be unable to deal in, or otherwise commercialize, itolizumab (EQ001). In that case, we would be required to cease operations related to itolizumab (EQ001), which would materially and adversely affect our financial condition and business prospects. In addition, in the absence of the general or specific license, the transfer, sale and/or purchase of our securities could be prohibited, and the ownership or possession of our securities could be subject to an affirmative OFAC reporting requirement relating to blocked property. Any violations of the CACR or other applicable export control and sanctions laws could subject us and certain of our employees to substantial civil or criminal penalties.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and may have a significant adverse effect on our business and results of operations.

There have been, and continue to be, numerous legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Affordable Care Act substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. For example, the Affordable Care Act: increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid-managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs; implemented 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; expanded eligibility criteria for Medicaid programs; created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation, or CMMI, at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.
There have been judicial, Congressional and executive challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. We are continuing to monitor any changes to the Affordable Care Act that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by CMMI which will be evaluated on their ability to lower the cost of drugs, promote

accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The IRA's drug pricing reforms have the potential to adversely impact our ability to successfully commercialize our product candidates and could lessen the real or perceived value of our product candidates, which would negatively impact our business.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

If any of our services providers are characterized as employees, we would be subject to employment and tax withholding liabilities and other additional costs.

We rely on independent contractors to provide certain services to us. We structure our relationships with these outside services providers in a manner that we believe results in an independent contractor relationship, not an employee relationship. An independent contractor is generally distinguished from an employee by his or her degree of autonomy and independence in providing services. A high degree of autonomy and independence is generally indicative of an independent contractor relationship, while a high degree of control is generally indicative of an employment relationship. Tax or other regulatory authorities may challenge our characterization of services providers as independent contractors both under existing laws and regulations and under laws and regulations adopted in the future. We are aware of a number of judicial decisions and legislative proposals that could bring about major changes in the way workers are classified, including the California legislature's passage of California Assembly Bill 5, which California Governor Gavin Newsom signed into law in September 2019, or AB 5, and Assembly Bill 2257, or AB 2257, which went into effect in September 2020 and amended certain portions of AB 5. AB 5 and AB 2257 are often referred to collectively simply as AB 5. AB 5 purports to codify the holding of the California Supreme Court's unanimous decision in Dynamex Operations West, Inc. v. Superior Court of Los Angeles, which introduced a new test for determining worker classification that is widely viewed as expanding the scope of employee relationships and narrowing the scope of independent contractor relationships. While AB 5 exempts certain licensed health care professionals, including physicians and psychologists, not all of our independent contractors work in exempt occupations. There has been little guidance from the regulatory authorities charged with enforcing AB 5, and there is a significant degree of uncertainty regarding its application. In addition, AB 5 has been the subject of widespread national discussion and it is possible that other jurisdictions might enact similar laws. As a result, there is significant uncertainty regarding what the state, federal and foreign worker classification regulatory landscape will look like in future years. The current economic climate indicates that the debate over worker classification will continue for the foreseeable future. If such regulatory authorities or state, federal or foreign courts were to determine that our services providers are employees and not independent contractors, we would, among other things, be required to withhold income taxes, to withhold and pay Social Security, Medicare and similar taxes, to pay unemployment and other related payroll taxes, and to provide certain employee benefits. We could also be liable for unpaid past taxes and other costs and subject to penalties. As a result, any determination that the service providers we characterize as independent contractors should be classified as employees could adversely impact our business, financial condition and results of operations.

We may be subject to applicable foreign, federal and state fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any future product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or

other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA;

- federal civil and criminal false claims laws, such as the FCA which can be enforced by private citizens, on behalf of the government, through civil qui tam actions, and civil monetary penalty laws prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment or approval by the federal government, including federal health care programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product, providing consulting fees and other benefits to physicians to induce them to prescribe products, engaging in promotion for "off-label" uses, and submitting inflated best price information to the Medicaid Rebate Program;

- HIPAA, among other things, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and their subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the U.S. federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the Public Health Service Act, which prohibits, among other things, the introduction of a biological product into interstate commerce without an approved BLA;

• federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

• the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians, as defined by such law, other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;

• state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and

• state and foreign laws that require pharmaceutical companies to implement compliance programs and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; track and report gifts, compensation and other remuneration provided to physicians, other health care providers, and certain health care entities; report information related to drug pricing; and/or ensure the registration and compliance of sales personnel. In addition, we may be subject to federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of EQ101, EQ302, itolizumab (EQ001) and any future product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of EQ101, EQ302, itolizumab (EQ001) or any future product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with physicians, some of whom received stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. Responding to investigations can be time and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to certain U.S. and certain foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, or collectively Trade Laws, prohibit, among other things, companies and their employees, agents, CROs, legal counsel,

accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on contract service providers for research, preclinical studies, and clinical studies and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Ownership of our Common Stock

The stock price of our common stock may be volatile or may decline regardless of our operating performance, and you could lose all or part of your investment.

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

- our operating performance and the performance of other similar companies;
- our ability to enroll and retain subjects in our ongoing and future clinical studies;
- results from our ongoing and future clinical studies with our current and future product candidates, and the results of the clinical studies of our competitors or of Biocon;
- adverse events observed in our clinical studies or in the clinical studies, exploratory studies, or other clinical uses of itolizumab supported by Biocon or third parties or during post-approval use of itolizumab;
- the timing of data from our ongoing and planned clinical studies of EQ101 and itolizumab (EQ001);
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments of ours, our competitors' or Biocon's;
- the level of expenses related to future product candidates or clinical development programs;
- changes in the structure of healthcare payment systems;
- our ability to achieve product development goals in the timeframe we announce;
- announcements of clinical study results, regulatory developments, acquisitions or mergers, strategic alliances or significant agreements by us, by our competitors, or by Biocon;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a substantial proportion of our outstanding common stock;
- the size of our market float;
- our implementation and execution of a stock repurchase program;
- delays or other adverse impacts to our clinical studies from global health epidemics or outbreaks;
- taxation authorities, such as the IRS and ATO, disagreeing with the positions taken on our tax returns; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations, including as a result of the COVID-19 pandemic, bank failures, the conflict between Russia and Ukraine, and the conflict in the Middle East, that have affected

and may continue to affect the market prices of equity securities of many life sciences companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements, such as our Asset Purchase Agreement with Ono. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. In October 2023, we entered into the 2023 ATM Facility with Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $21.95 million from time to time through Jefferies acting as our sales agent. As of the filing of this Annual Report on Form 10-K, we have not sold any shares under the 2023 ATM Facility.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through collaboration and license agreements with third parties, such as our Asset Purchase Agreement with Ono, 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 through equity or debt financings 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 prefer to develop and market ourselves.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, it is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

While we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of the matters relating to SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed

access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of March 20, 2024, we had 35,254,752 shares of our common stock outstanding. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or Securities Act. We have registered shares of common stock that we have issued and may issue under our employee equity incentive plans, which shares may be sold freely in the public market upon issuance. Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for other stockholders to sell shares of our common stock.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially own a significant percentage of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

We cannot guarantee that our stock repurchase program will be further consummated or will enhance stockholder value, and share repurchases could affect the price of our common stock.

In July 2023, our board of directors authorized a stock repurchase program pursuant to which we may repurchase up to $7.5 million of shares of our common stock through December 31, 2024. Under the stock repurchase program, we may repurchase shares of common stock during the term of the stock repurchase program through open market transactions or such other transactions as our board of directors or designated committee thereof may approve from time to time. As of December 31, 2023, we have repurchased 298,385 shares of our common stock under the stock repurchase program for a total of $0.3 million. There have been no repurchases of our common stock under the stock repurchase program since December 31, 2023 and through the date of the filing of this Annual Report on Form 10-K. There can be no assurances that we will make further stock repurchases in the future.

Open market repurchases will be structured to occur in accordance with applicable federal securities laws, including within the pricing and volume requirements of Rule 10b-18 under the Exchange Act. We may also, from time to time, enter into Rule 10b5-1 plans to facilitate repurchases of our shares of common stock under this authorization. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our common stock, alternative investment opportunities, our cash resources, restrictions under any of our agreements, corporate and regulatory requirements and market conditions.

Repurchases of shares of common stock could affect the market price of our common stock, increase their volatility or diminish our cash reserves, which may impact our ability to finance our future operations. Although our stock repurchase program is intended to enhance long-term stockholder value, there is no assurance that it will do so, and short-term share price fluctuations could reduce the program's effectiveness.

In addition, any future stock repurchases will likely reduce our "public float," (i.e., the number of shares of our common stock that are owned by non-affiliated stockholders and available for trading in the securities markets). A reduction in our public float may reduce the volume of trading in our shares of common stock and result in reduced liquidity, which, in each case, may cause fluctuations in the trading price of our common stock unrelated to our performance.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law; (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock. In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware

corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums 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 amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- 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 under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state study courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

As a public company in the United States, we incur significant legal and financial compliance costs and we are subject to the Sarbanes-Oxley Act. We can provide no assurance that we will, at all times, in the future be able to report that our internal controls over financial reporting are effective.

Companies that file reports with the SEC, including us, are subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires management to establish and maintain a system of internal control over financial reporting, and annual reports on Form 10-K filed under the Exchange Act must contain a report from management assessing the effectiveness of a company's internal control over financial reporting. Ensuring that we have adequate internal financial and

accounting controls and procedures in place to produce accurate financial statements on a timely basis remains a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause our stock price to decline as a result.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The Nasdaq Capital Market or other regulatory authorities.

Furthermore, stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, any new regulations or disclosure obligations may increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We or the parties upon whom we depend on may be adversely affected by earthquakes, fires, other natural disasters, or other sudden, unforeseen and severe adverse events, including public health epidemics or outbreaks, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our headquarters and main research facility are located in the Greater San Diego Area, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third party service provider 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, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events, including public health epidemics or outbreaks, that could impact our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical studies, our development plans and business. For example, in March 2020, due to the spread of the coronavirus, the Indian government restricted the export of 26 active pharmaceutical ingredients and the medicines made from them. These export restrictions are indefinite and may be modified or expanded. If the export restrictions are expanded to include itolizumab (EQ001), our supply of itolizumab (EQ001) may be disrupted, delayed or stopped indefinitely and our ability to continue development of itolizumab (EQ001), including our ongoing clinical studies, may be significantly impacted and may result in higher costs of drug product and adversely harm our business.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our research programs and product candidates. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or USPTO rules and regulations could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. 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, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future

patents, and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of EQ101, itolizumab (EQ001) and any future product candidates in human clinical studies and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that EQ101, itolizumab (EQ001) or any future product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or termination of clinical studies;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical study subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to clinical study subjects or patients;
- product recalls, withdrawals or labeling, or marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently have product liability insurance. However, the amount of insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as EQ101, EQ302, itolizumab (EQ001) and any future product candidates advance through clinical studies and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on December 22, 2017, U.S. federal income tax legislation was signed into law (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018"), informally titled the Tax Cuts and Jobs Act, that significantly revised the IRC. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation.

Effective January 1, 2022, the Tax Cuts and Jobs Act modified IRC 174 to require taxpayers' U.S. based and non-U.S. based research and experimental (R&E) expenditures to be capitalized and amortized over a period of five or fifteen years, respectively. Prior to the Tax Cuts and Job Act amendment, Section 174 allowed taxpayers to either immediately deduct R&E expenditures in the year paid or incurred, or elect to capitalize and amortize over a period of at least 60 months. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, it could

harm our future operating results by effectively increasing our future tax obligations. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur, whether we achieve sufficient income to fully utilize such deductions and whether we conduct our research and development activities inside or outside the United States.

Legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, modified certain provisions of the Tax Cuts and Jobs Act. In addition, the recently enacted IRA includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act or the IRA. We do not expect the Tax Cuts and Jobs Act or the CARES Act to have a material impact on our current projection of minimal cash taxes for the near future. However, we continue to examine the impact that the Tax Cuts and Jobs Act, the CARES Act and the IRA may have on our business in the longer term. We urge prospective investors to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

We are subject to risks related to taxation in multiple jurisdictions.

We are subject to income taxes in the United States and various state jurisdictions, as well as Australia. The preparation of these income tax returns requires us to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid. Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We periodically assess the likelihood and amount of potential revisions and, if warranted, adjust the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known. An amount is accrued for the estimate of additional tax liability, if any, including interest and penalties, for any uncertain tax positions taken or expected to be taken in an income tax return. Significant judgments based on interpretations of existing tax laws or regulations are required in determining the provision for income taxes. Our provision for income taxes could be adversely affected by various factors, including, but not limited to, changes in the mix of earnings in tax jurisdictions with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in existing tax policies, laws, regulations, or rates, changes in the level of non-deductible expenses (including stock-based compensation), location of operations, changes in our future levels of research and development spending, mergers and acquisitions, or the result of examinations by various tax authorities. Although we believe our tax estimates are reasonable, if the Internal Revenue Service or other taxing authority disagrees with the positions taken on our tax returns, we could have additional tax liability, including interest and penalties. If material, payment of such additional amounts upon final adjudication of any disputes could have a material impact on our results of operations and financial position.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

We are a "smaller reporting company" and a "non-accelerated filer" and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to smaller reporting companies or non-accelerated filers could make our common stock less attractive to investors.

We are a "smaller reporting company" and a "non-accelerated filer" as defined in the Exchange Act, and for as long as we continue to be a "smaller reporting company" or a "non-accelerated filer," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "smaller reporting companies" or "non-accelerated filers," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 (for so long as we are a "non-accelerated filer") and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements (for so long as we are a "smaller reporting company"). We expect to be both a "smaller reporting company" and a "non-accelerated filer" in 2024. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant

stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, lab equipment, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical studies and employees, or Information Systems and Data.

We engage an external Head of Information Technology consultant to work with the company, including the Chief Operating Officer, Chief Financial Officer, and Executive Leadership Team, to help identify, assess and manage the company's cybersecurity threats and risks. This group identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident response plan and/or incident response policy, data and information protection plans, network security and access controls for certain systems, encryption of data, systems monitoring, cyber insurance and employee training.

Our assessment and management of material risks from cybersecurity threats are integrated into the company's overall risk management processes. For example, the Head of Information Technology works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We may use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example, professional services firms (including legal counsel) and threat intelligence service providers.

To operate our business, we utilize certain third-party service providers to perform a variety of functions, such as outsourced business critical functions, clinical research, professional services, Software-as-a-Service (SaaS) platforms, managed services, cloud-based infrastructure, encryption and authentication technology, corporate productivity services, and other functions. We have certain vendor management processes to help manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity and quantity of information processed, and the identity of the service provider, our vendor management process may include reviewing the cybersecurity practices of such provider, contractually imposing obligations on the provider related to the services they provide and/or the information they process, requiring their completion of written questionnaires regarding their services and data handling practices and conducting periodic re-assessments during their engagement.

For a description of the risks from cybersecurity threats that may materially affect the company and how they may do so, please see "Risk Factors – Risks Related to Employees, Managing Our Growth and Other Legal Matters."

Governance

Our board of directors addresses the company's cybersecurity risk management as part of its general oversight function. The audit committee of the board of directors is responsible for reviewing the company's guidelines and policies with respect to risk assessment and risk management, including those related to assessment and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain company management, including our Head of IT, who holds a Microsoft Certification, and our Chief Operating Officer, who earned a Cybersecurity for Directors certificate from the Corporate Governance Institute.

Management is also responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the company's overall risk management strategy, and communicating key priorities to relevant personnel. The Head of IT and Chief Operating Officer are responsible for helping prepare the company for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances and designated risk level, including the Chief Financial Officer, Chief Executive Officer and/or full Executive Leadership Team, who participates in our disclosure controls and procedures. The Head of IT and Chief Operating Officer work with the company's incident response team to help the company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the company's incident response processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from the Head of IT and Chief Operating Officer concerning the company's significant cybersecurity threats and risk and the processes the company has implemented to address them. The audit committee also receives summaries or presentations related to the company's information systems and data and cybersecurity threats, risk and mitigation.

Item 2. Properties.

We lease approximately 1,750 square feet of space for our current headquarters in La Jolla, California under a lease that expires in February 2027. We also lease additional office and laboratory spaces in La Jolla, California, under leases with various expiration dates, with the first expiring in February 2025 and the latest extending through February 2027. We had been leasing office space in South San Francisco, California which expired at the end of February 2023 and was not renewed.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on the Nasdaq Global Market under the symbol "EQ" on October 12, 2018, and was transferred to the Nasdaq Capital Market under the same symbol on September 15, 2023. Prior to October 12, 2018, there was no public trading market for our common stock.

Holders of Record

As of March 20, 2024, there were approximately 50 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

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

Securities Authorized for Issuance Under Our Equity Compensation Plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In July 2023, our board of directors authorized a stock repurchase program, or Stock Repurchase Program, pursuant to which we may repurchase up to $7.5 million of shares of our common stock through December 31, 2024. As of December 31, 2023, approximately $7.2 million remained available under our Stock Repurchase Program for future repurchases.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Financial Data" and our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in the section entitled "Risk Factors" and in other parts of this Annual Report on Form 10-K. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biotechnology company leveraging a deep understanding of immunobiology to develop novel therapeutics to treat severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need. Our strategy is focused on advancing the clinical development of our product candidates, including potentially pursuing additional indications and acquiring new product candidates and platforms to expand our pipeline. We intend to commercialize our product candidates either independently or through partnerships or otherwise monetize our pipeline through strategic transactions.

Our current clinical-stage product candidates consist of EQ101 and itolizumab (EQ001). EQ101 is a first-in-class, selective, tri-specific synthetic peptide engineered to specifically inhibit IL-2, IL-9 and IL-15, key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immuno-inflammatory indications. Itolizumab (EQ001) is a first-in-class monoclonal antibody that selectively targets the immune checkpoint receptor CD6, which plays a central role in the modulation of effector T cell, or T_{eff} cell, activity and trafficking that drives a number of immuno-inflammatory diseases across multiple therapeutic areas. We are also engaged in the discovery and optimization of additional peptide-based product candidates that selectively target multiple cytokines and are currently advancing the preclinical development of EQ302, a first-in-class, orally delivered, bi-specific inhibitor of IL-15 and IL-21. Our novel and differentiated pipeline of first-in-class immunology assets has the potential to address unmet medical needs in numerous areas, including dermatology, gastroenterology, rheumatology, hematology, transplant science, oncology and pulmonology. We are focused on developing EQ101, EQ302 and itolizumab (EQ001) as potential best-in-class, disease modifying treatments for multiple severe immuno-inflammatory disorders.

We acquired the exclusive worldwide rights to EQ101 and a proprietary platform for discovering additional, novel multi-cytokine targeting product candidates such as EQ302 through the acquisition of Bioniz Therapeutics, Inc., or Bioniz, in February 2022. EQ101 and EQ302 are synthetic peptides engineered to specifically inhibit key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs in a number of immuno-inflammatory indications. In November 2022, we initiated a Phase 2 proof-of-concept clinical study of EQ101 administered intravenously, or IV, in subjects with moderate to severe alopecia areata, or AA, in Australia and New Zealand. Enrollment in that study has been completed, and we expect to announce topline data in the second quarter of 2024. We are currently conducting preclinical development of EQ302, including in vivo pharmacology and formulation development, to further characterize and optimize the product candidate. Pending positive findings, we expect to advance EQ302 into additional preclinical development to include GMP-manufacturing and toxicology studies capable of supporting a potential IND filing and advancement into a first-in-human clinical study.

We recently completed a Phase 1 first-in-human clinical study of another multi-cytokine targeting peptide, EQ102, in healthy volunteers in Australia. EQ102 is a bi-specific inhibitor of IL-15 and IL-21, which was also acquired as part of the Bioniz acquisition. In that Phase 1 study, EQ102 was generally well tolerated and demonstrated pharmacodynamic activity, but the bioavailability of the initial formulation was lower than expected. Preclinical and translational data have demonstrated that EQ302 has increased potency compared to EQ102, is both stable and permeable in the gut, and can be further modified for optimal systemic or gut-restricted activity. In December 2023, we announced that given our recent progress with EQ302 and its superior product profile relative to EQ102, we have transitioned away from further developing EQ102 and are instead advancing EQ302 towards the clinic for the potential treatment of patients with gastrointestinal and skin diseases.

We acquired our rights to itolizumab (EQ001) pursuant to a collaboration and license agreement with Biocon SA (subsequently assigned to Biocon Limited, or together, Biocon) in May 2017, which has been subsequently amended, or Biocon License. In March 2022, we initiated EQUATOR, a global Phase 3 pivotal clinical study of itolizumab (EQ001) in 200 patients with acute graft-versus-host disease, or aGVHD. The decision to initiate the EQUATOR study was based on findings from our completed Phase 1b clinical study in aGVHD, called EQUATE, and feedback from both the U.S. Food and Drug Administration, or FDA, and leading physicians in the field of hematopoietic stem cell transplantation. We expect the

interim review of EQUATOR data of the first 100 subjects by the Data Safety Monitoring Committee will occur in the third quarter of 2024. We recently completed EQUALISE, a Phase 1b proof-of-concept clinical study of itolizumab (EQ001) in patients with systemic lupus erythematosus, or SLE, and lupus nephritis, or LN. In November 2023, we announced data from the Type B LN portion of the study presented at the annual meetings of the American College of Rheumatology and the American Society of Nephrology. That data represented all but the last patient in the follow-up period and demonstrated that itolizumab (EQ001) was well-tolerated and produced a clinically meaningful response in highly proteinuric subjects. We expect to provide the topline data from the Type B LN portion of EQUALISE to Ono Pharmaceutical Co., Ltd., or Ono, in the coming weeks.

We are also collaborating with Biocon and co-funding a Phase 2 clinical study of itolizumab in subjects with ulcerative colitis. The study, which is being conducted by Biocon in India and commenced in November 2022, is a randomized, double-blinded, placebo-controlled clinical study in up to 90 subjects, to evaluate the safety and efficacy of itolizumab in patients with moderate to severe ulcerative colitis.

On December 5, 2022, we entered into the Asset Purchase Agreement with Ono pursuant to which we granted Ono an exclusive option to acquire our rights to itolizumab (EQ001) or the Option. These rights include all therapeutic indications and the rights to commercialize itolizumab (EQ001) in the United States, Canada, Australia, and New Zealand. In exchange for the Option, Ono paid us a one-time, upfront payment of an amount equal to JPY 3.5 billion, or $26.4 million.

If Ono exercises the Option, Ono will pay us a one-time, payment of an amount equal to JPY 5.0 billion, or approximately $33.1 million based on the currency exchange rate quoted by MUFG Bank, Ltd on March 21, 2024. We expect Ono to make its option exercise decision in the second half of 2024. We are also eligible to receive up to $101.4 million upon the achievement of certain development and commercialization milestones.

Pursuant to the Asset Purchase Agreement, we are responsible for conducting all research and development of itolizumab (EQ001), which is being funded by Ono on a quarterly basis from July 1, 2022 through the option period. Unless terminated early, the option period will expire three months following the delivery of topline data from the EQUALISE clinical study in LN and interim data from the EQUATOR Phase 3 clinical study in aGVHD.

The Asset Purchase Agreement can be terminated at any time by Ono upon written notice, provided that in limited circumstances Ono will be obligated to continue to reimburse us for research and development costs and expenses of itolizumab (EQ001) for a certain period of time following such termination. If Ono does not timely exercise its Option, the Asset Purchase Agreement and the Option will automatically terminate. The Asset Purchase Agreement also contains customary termination rights for both parties for material breach and an outside date (subject to limited adjustments) that permits either party to terminate the Asset Purchase Agreement if the closing has not occurred by December 31, 2025.

We have a proprietary product discovery platform that we can leverage to design novel peptides to target and inhibit multiple cytokines that are involved in validated biological and disease pathways. For example, we recently highlighted preclinical data from EQ302, a second generation orally deliverable multi-cytokine inhibitor in development to target IL-15 and IL-21. We also have ongoing translational biology programs to assess the therapeutic utility of our product candidates in additional indications where the mechanism of action is believed to play an important role in the pathogenesis of a particular disease. Our selection of current and future indications is driven by our analysis of the scientific, translational, clinical and commercial rationale for advancing our product candidates into further development.

Since our inception, substantially all of our efforts have been focused on organizing and staffing our company, business planning, raising capital, in-licensing rights to itolizumab (EQ001), conducting non-clinical research, filing three Investigational New Drug applications, or INDs, conducting clinical development of our product candidates, conducting business development activities such as the acquisition of Bioniz, the Asset Purchase Agreement with Ono and other transactions not completed, initiating a stock repurchase program, and the general and administrative activities associated with operating a public company. Furthermore, in connection with the acquisition of Bioniz, we expanded our pipeline from one product candidate to multiple product candidates, all at various stages of development. This expansion may accelerate the rate at which our operating losses increase as we incur costs to further the development and seek regulatory approval for these product candidates. We have generated revenue from the Asset Purchase Agreement related to the one-time, upfront payment from Ono in exchange for the Option as well as from the itolizumab (EQ001) development funding from Ono. We have not generated any revenue from product sales, milestone payments or royalties. Since inception, we have primarily financed our operations through debt and equity financings and revenue generated from the Asset Purchase Agreement.

We have incurred losses since our inception. For the years ended December 31, 2023 and 2022, our net losses were $13.3 million and $62.4 million, respectively. As of December 31, 2023, we had an accumulated deficit of $185.7 million.

Substantially all of our operating losses resulted from expenses incurred in connection with our research and development activities, non-clinical and clinical activities, acquired in-process research and development, and general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing losses into the foreseeable future. We anticipate our expenses will increase substantially as we advance our research and development activities, including the ongoing and future clinical development of EQ101, EQ302 and itolizumab (EQ001), potentially expand the indications in which we conduct clinical development of our product candidates, potentially acquire or develop new product candidates, including preclinical drug candidates identified through our multi-cytokine targeting drug discovery platform, seek regulatory approval for and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, and incur general corporate costs. We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2023, will enable us to fund our operations into the second half of 2025, assuming no further repurchases under our stock repurchase program.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for EQ101, EQ302, or any future product candidate, which is unlikely to happen within the next 12 months, if ever. Further, under the Asset Purchase Agreement with Ono, our revenues related to itolizumab (EQ001) are limited to the upfront option fee already received, reimbursement of our development costs of itolizumab (EQ001) during the option period, and the potential option exercise fee and potential milestone payments. If Ono does not exercise its Option, we would not expect to generate any revenues from product sales of itolizumab (EQ001) unless and until we successfully complete development and obtain regulatory approval for itolizumab (EQ001), which is unlikely to happen within the next 12 months, if ever. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements, such as our Asset Purchase Agreement with Ono. However, we may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. As a result of the conflict between Russia and Ukraine, the conflict in the Middle East, bank failures, inflationary pressures on the economy and monetary policy responses by government agencies and other macroeconomic factors, the global credit and financial markets have experienced extreme volatility, including from bank failures, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth and uncertainty about economic stability. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Financial Overview

Revenue

To date, we have not generated any revenues from therapeutic product sales, developmental milestones or royalties. In 2022 and 2023, our revenues were derived from an upfront payment under the Asset Purchase Agreement as well as from development funding from Ono. In the future, we may generate revenue from collaboration or license agreements we may enter into with respect to our product candidates, including further revenue such as development funding and potential option exercise and milestone payments from the Asset Purchase Agreement, as well as product sales from any approved product, which approval is unlikely to happen within the next 12 months, if ever. Our ability to generate product revenues will depend on the successful development and eventual commercialization of EQ101, EQ302, itolizumab (EQ001) if Ono does not exercise its option, and any future product candidates. If we fail to complete the development of EQ101, EQ302, itolizumab (EQ001) or any future product candidates in a timely manner, or to obtain regulatory approval for our product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected.

Asset Purchase Agreement with Ono Pharmaceutical Co., Ltd.

On December 5, 2022, we entered into the Asset Purchase Agreement pursuant to which we granted Ono the Option in exchange for a one-time, upfront payment of an amount equal to JPY 3.5 billion, or $26.4 million. These rights include all therapeutic indications and the rights to commercialize itolizumab in the United States, Canada, Australia, and New Zealand.

If Ono exercises the Option, we will receive JPY 5.0 billion, or approximately $33.1 million based on the currency exchange rate quoted by MUFG Bank, Ltd. on March 21, 2024. We are also eligible to receive up to $101.4 million upon achievement of certain development and commercialization milestones.

We are responsible for conducting all research and development of itolizumab, which is being funded by Ono on a quarterly basis from July 1, 2022, through the option period. Unless terminated early, the option period will expire three months

following the delivery of topline data from the EQUALISE clinical study in LN and interim data from the EQUATOR Phase 3 clinical study in aGVHD.

During the year ended December 31, 2023, we recognized $36.1 million of revenue under our Asset Purchase Agreement with Ono consisting of $27.0 million of development funding and $9.1 million related to the amortization of the upfront payment.

As of December 31, 2023, aggregate deferred revenue related to the Asset Purchase Agreement was $15.7 million.

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our non-clinical research and clinical development of our product candidates. Our research and development expenses include:

- salaries and other related costs, including stock-based compensation and benefits, for personnel in research and development functions;
- per patient clinical study costs;
- external research and development expenses incurred under arrangements with third parties, such as consultants and advisors for research and development;
- costs of services performed by third parties, such as contract research organizations, or CROs, that conduct research and development activities on our behalf;
- costs related to preparing and filing three INDs with the FDA and other regulatory interactions and submissions;
- pharmacovigilance costs related to global drug safety monitoring and reporting;
- external expenses related to chemistry, manufacturing, and controls, or CMC, and supply of drug product; and
- costs related to general overhead expenses such as travel, insurance, rent expenses, lab supplies and equipment associated with our research and development activities.

We expense research and development costs as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

Our direct research and development expenses consist principally of external costs, such as fees paid to CROs and consultants in connection with our non-clinical research and clinical development.

We recognize the Australian Research and Development Tax Incentive, or the Tax Incentive, as a reduction of research and development expense. The amounts are determined based on our eligible research and development expenditures and are non-refundable, provided that in order to qualify for the Tax Incentive the filing entity must have revenue of less than AUD $20.0 million during the tax year for which a reimbursement claim is made and cannot be controlled by an income tax exempt entity. The Tax Incentive is recognized when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured or reliably estimated.

We plan to substantially increase our research and development expenses for the foreseeable future as we advance the development of EQ101, EQ302, and itolizumab (EQ001) if Ono does not exercise its option, potentially expand the number of indications for which we are developing those product candidates, and potentially acquire or develop new product candidates. The successful development of EQ101, EQ302 and itolizumab (EQ001) is highly uncertain. At this time, due to the inherently unpredictable nature of pre-clinical and clinical development, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of our product candidates or the period, if any, in which material net cash inflows from the sales from our product candidates may commence. Clinical development timelines, the probability of success, and development costs can differ materially from expectations.

Completion of clinical studies may take several years or more, and the length of time generally varies according to the type, complexity, novelty, and intended use of a product candidate. The cost of clinical studies may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- per patient clinical study costs;
- the number of clinical studies required for approval;
- the number of sites and the number of countries included in our clinical studies;
- the length of time required to enroll suitable patients;
- the inefficiencies and additional costs related to any delays and potential restarts of clinical studies;
- the number of doses that patients receive;
- the number of patients that participate in our clinical studies;
- the drop-out or discontinuation rates of patients in our clinical studies;
- the duration of patient follow-up;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number and complexity of procedures, analyses and tests performed during our clinical studies;
- the costs of procuring drug product for our clinical studies;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense consist of the cost to acquire the rights to develop new product candidates associated with the Bioniz acquisition as those product candidates acquired were deemed to have no alternative future use.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation and benefits, and consulting fees for executive, human resources, investor relations, finance, and accounting functions. Other significant costs include legal fees relating to patent and corporate matters, insurance, travel, board expenses, facility costs and taxes.

We anticipate that our general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, increased legal, audit, tax and other professional fees associated with being a public company and maintaining compliance with stock exchange listing and SEC requirements, director and officer insurance premiums associated with being a public company, and accounting and investor relations costs. In addition, if we obtain regulatory approval for any product candidate, we expect to incur expenses associated with building the infrastructure and capabilities to commercialize such product. However, the timing of any such approval is highly uncertain, and it may be several years, if ever, that we receive any such regulatory approval.

Interest Expense

Interest expense consists of interest and amortization of discounts on our prior term loans payable.

Interest Income

Interest income consists primarily of interest income earned on cash, cash equivalents and short-term investments, and is recognized when earned.

Other (Expense) Income, Net

Other (expense) income, net consists primarily of foreign currency transaction gains and losses related to our Australian subsidiary.

Income Tax Expense

Income tax expense consists of federal and state income tax expense.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Revenue	$ 36,084	$ 15,759	$ 20,325
Research and development	37,039	37,547	(508)
Acquired in-process research and development	-	23,049	(23,049)
General and administrative	13,567	17,239	(3,672)
Interest expense	(491)	(1,053)	562
Interest income	2,334	420	1,914
Other (expense) income, net	(76)	281	(357)
Income tax expense	580	-	580

Revenue

During the year ended December 31, 2023, we recognized revenue of $36.1 million under our Asset Purchase Agreement with Ono. For the year ended December 31, 2023, development funding represented $27.0 million and amortization of the upfront payment represented $9.1 million. During the year ended December 31, 2022, we recognized revenue of $15.8 million under our Asset Purchase Agreement with Ono. Amortization of the upfront payment represented $4.0 million, and development funding from July 1, 2022 through December 31, 2022, represented $11.8 million.

Research and Development Expenses

Research and development expenses were $37.0 million for the year ended December 31, 2023, compared to $37.5 million for the year ended December 31, 2022. The decrease in research and development expense primarily includes the following changes:

- $1.7 million decrease in non-clinical research expenses;
- $1.4 million decrease in employee compensation and benefits;
- $1.1 million increase in the estimated Tax Incentive benefit from the Australian Taxation Office, or ATO, offsetting our research and development expenses associated with our EQ101 and EQ102 clinical studies in Australia;
- $0.4 million decrease in transaction costs associated with the Bioniz asset acquisition, primarily legal expenses; offset by
- $3.7 million increase in clinical development expenses, primarily driven by EQUATOR, EQ101 and EQ102 clinical studies, partially offset by lower costs for our other itolizumab (EQ001) clinical studies; and
- $0.4 million increase in consulting expenses.

Acquired In-Process Research and Development Expenses

There were no acquired in-process research and development expenses in the year ended December 31, 2023, whereas there was $23.0 million of such expenses for the year ended December 31, 2022. The acquired in-process research and development expenses in the year ended December 31, 2022 resulted from accounting for the Bioniz acquisition as an asset acquisition based on a determination that the product candidates acquired had no alternative future use. The consideration in excess of the tangible net liabilities acquired was expensed.

General and Administrative Expenses

General and administrative expenses were $13.6 million for the year ended December 31, 2023, compared to $17.2 million for the year ended December 31, 2022. The decrease in general and administrative expense primarily includes the following changes:

- $2.1 million decrease in legal fees;
- $0.8 million decrease in employee compensation and benefits primarily driven by lower non-cash stock-based compensation expenses;
- $0.7 million decrease in consulting expenses;
- $0.6 million decrease in overhead related costs primarily driven by lower directors and officers insurance expenses; offset by
- $0.6 million increase in audit and tax professional fees.

Interest Expense

Interest expense was $0.5 million for the year ended December 31, 2023, compared to $1.1 million for the year ended 2022. Interest expense consists of interest on our prior term notes payable.

Interest Income

Interest income was $2.3 million for the year ended December 31, 2023, compared to $0.4 million for the year ended December 31, 2022. The increase in interest income was primarily due to higher average interest rates in 2023 compared to 2022.

Other (Expense) Income, Net

Other expense, net was $0.1 million for the year ended December 31, 2023, compared to other income, net of $0.3 million for the year ended December 31, 2022. For the year ended December 31, 2023, other expense, net consisted primarily of net realized foreign currency transaction losses related to our Australian subsidiary. For the year ended December 31, 2022, other income, net consisted of a realized foreign currency gain of $0.6 million on the Ono upfront payment of JPY 3.5 billion due to the strengthening of the Japanese Yen between the time of invoicing and cash receipt, partially offset by net unrealized foreign currency transaction losses related to the Australian subsidiary.

Income Tax Expense

Income tax expense was $0.6 million for the year ended December 31, 2023. Our 2023 income tax expense was primarily attributable to domestic cash tax expense resulting from differences between book and tax treatment of certain items. We do not record a deferred tax provision as there is a full valuation allowance offsetting our deferred tax assets. There was no income tax expense for the year ended December 31, 2022.

Liquidity and Capital Resources

From inception through December 31, 2023, we have financed our operations primarily through the sale of equity and debt securities. In addition, we have generated proceeds from our Asset Purchase Agreement with Ono as described in more detail in the Sources of Liquidity section below. As of December 31, 2023, we had an accumulated deficit of $185.7 million and anticipate that we will continue to incur net losses for the foreseeable future. As of December 31, 2023, we had $23.2 million in cash and cash equivalents and $17.7 million in short-term investments.

Sources of Liquidity

2023 ATM Facility

In October 2023, we entered into an at-the-market facility with Jefferies LLC, or Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $21.95 million from time to time through Jefferies acting as our sales agent, or the 2023 ATM Facility. As of the filing of this Annual Report on Form 10-K, we have not sold any shares under the 2023 ATM Facility.

Asset Purchase Agreement with Ono

On December 5, 2022, we entered into the Asset Purchase Agreement with Ono, pursuant to which we granted Ono the exclusive right, but not the obligation, to acquire our rights to itolizumab. These rights include all therapeutic indications and the rights to commercialize itolizumab in the United States, Canada, Australia, and New Zealand. In exchange for the Option, Ono paid us a one-time upfront payment of an amount equal to JPY 3.5 billion, or $26.4 million.

If Ono exercises the Option, Ono will pay us a one-time, payment of an amount equal to JPY 5.0 billion, or approximately $33.1 million based on the currency exchange rate quoted by MUFG Bank Ltd. on March 21, 2024.

We are also eligible to receive up to $101.4 million upon the achievement of certain development and commercialization milestones. As of December 31, 2023, we have not received the option exercise payment or any milestone payments.

We are responsible for conducting all research and development of itolizumab, which is being funded by Ono on a quarterly basis from July 1, 2022 through the option period. The option period will expire three months following the delivery of topline data from the EQUALISE study in LN and interim data from the EQUATOR Phase 3 clinical study in aGVHD.

As of December 31, 2023, we have received $38.0 million in development funding payments from Ono.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing and future activities, particularly as we advance and expand our clinical development of EQ101 and itolizumab (EQ001) if Ono does not exercise its option, including potential new indications, and potentially advance preclinical research of EQ302 and other novel preclinical drug candidates identified through our multi-cytokine targeting drug discovery platform. We expect that our primary uses of capital will be for clinical development services, non-clinical research, manufacturing and product supply, potential acquisition of new products, potential repurchases of shares of our common stock under our stock repurchase program, legal and other regulatory compliance expenses, employee compensation and related expenses, insurance premiums, working capital and other general overhead costs.

In July 2023, our board of directors authorized a stock repurchase program pursuant to which we may repurchase up to $7.5 million of shares of our common stock through December 31, 2024. Under the program, we may repurchase shares of common stock during the term of the program through open market transactions or such other transactions as our board of directors or designated committee thereof may approve from time to time. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our common stock, alternative investment opportunities, our cash resources, restrictions under any of our agreements, corporate and regulatory requirements and market conditions. As of December 31, 2023, we repurchased 298,385 shares of our common stock under the stock repurchase program for a total of $0.3 million. There have been no repurchases of our common stock under the stock repurchase program since December 31, 2023 and through the date of the filing of this Annual Report on Form 10-K. We expect to fund any future repurchase of shares of our common stock, if any, under the program with existing cash and cash equivalents.

We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2023 will enable us to fund our currently planned operations into the second half of 2025, assuming no further repurchases under our stock repurchase program. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Furthermore, our operating plans may change, and we may need additional funds sooner than planned. Additionally, the process of testing product candidates in clinical studies is costly, and the timing of progress in these studies is uncertain. Because the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of EQ101, EQ302 and itolizumab (EQ001) or any of our other product candidates or whether, or when, we may achieve profitability.

Our future capital requirements will depend on many factors, including:

- whether Ono exercises its option and the extent to which milestones payments, if any, are received:
- the initiation, progress, timing, costs and results of our ongoing and future clinical studies of EQ101 and itolizumab (EQ001) and other product candidates, including as such activities may be adversely impacted by public health

epidemics or outbreaks, the evolving conflict between Russia and Ukraine, the conflict in the Middle East and bank failures;

- the potential advancement and cost of preclinical research of EQ302 and other novel preclinical drug candidates identified by our multi-cytokine targeting drug discovery platform;
- the number and scope of indications we decide to pursue for the development of our product candidates;
- the cost, timing and outcome of regulatory review of any Biologics License Application, or BLA, or New Drug Application, or NDA, we may submit for our product candidates;
- the costs and timing of manufacturing EQ101 and itolizumab (EQ001) and other product candidates;
- the costs of drug formulation research and device development;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- our ability to enter into partnerships or otherwise monetize our pipeline through strategic transactions on a timely basis, on terms that are favorable to us, or at all;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies or engage in in-house discovery and preclinical research of new product candidates, for example EQ302;
- the legal and other transactional costs associated with our business development activities; and
- the cost associated with commercializing EQ101 and itolizumab (EQ001) or any of our other product candidates, if approved for commercial sale.

Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements, such as our Asset Purchase Agreement with Ono. The sale of additional equity or convertible debt could result in additional dilution to our stockholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. The incurrence of debt financing would result in debt service obligations and the governing documents would likely include operating and financing covenants that would restrict our operations. As a result of the conflict between Russia and Ukraine, the conflict in the Middle East, bank failures, inflationary pressures on the economy and monetary policy responses taken by government agencies and other macroeconomic factors, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we raise additional funds through collaboration or license agreements, 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 and/or that may reduce the value of our common stock. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations. Any of these actions could have a material effect on our business, financial condition and results of operations. We have experienced net losses and negative cash flows from operating activities since our inception and expect to continue to incur net losses into the foreseeable future. We had an accumulated deficit of $185.7 million as of December 31, 2023. We expect operating losses and negative cash flows to continue for at least the next several years as we incur costs related to the development of EQ101, EQ302 and itolizumab (EQ001) if Ono does not exercise its option, and any of our other product candidates.

Material Cash Requirements

Our expected material cash requirements are comprised of contractually obligated expenditures, including amounts due under our operating leases. For additional information relating to our leases, see Notes 7 and 12 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K. We have no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase order basis. Our expected material cash requirements do not include potential contingent payments upon the achievement by us of regulatory and commercial milestones that we may be required to make under the terms of the merger agreement pursuant to which we acquired Bioniz, nor do they include potential contingent payments upon the achievement by us of regulatory and commercial milestones or royalty payments that we may be required to make under license agreements we have entered into or may enter into with various entities pursuant to which we have in-licensed certain intellectual property, including the Biocon License. For further details on the potential contingent payments related to our acquisition of Bioniz and related to the Biocon License, see Notes 6 and 9 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net cash (used in) provided by:		
Operating activities	$ (21,783)	$ (8,733)
Investing activities	(4,762)	18,684
Financing activities	(9,228)	(1,215)
Effect of exchange rate changes on cash	(118)	5
Net (decrease) increase in cash and cash equivalents	$ (35,891)	$ 8,741

Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was $21.8 million compared to $8.7 million during the year ended December 31, 2022. The primary drivers of the change in net cash used in operating activities pertained to a decrease of $26.4 million related to the one-time receipt of the upfront payment from Ono received in connection with entering into the Asset Purchase Agreement in December 2022 partially offset by an increase of $13.7 million in development funding from Ono.

Investing Activities

Net cash used in investing activities was $4.8 million during the year ended December 31, 2023. Purchases of our short-term investments totaled $54.7 million, which was offset by maturities of short-term investments totaling $50.0 million during the period. Purchases of property and equipment for the year ended December 31, 2023 totaled $0.1 million.

Net cash provided by investing activities was $18.7 million during the year ended December 31, 2022. Maturities of our short-term investments totaled $33.2 million, which was offset by purchases of short-term investments totaling $14.9 million. Purchases of property and equipment for the year ended December 31, 2022 totaled $0.3 million. As a result of the Bioniz acquisition, we acquired cash totaling $0.7 million.

Financing Activities

Net cash used in financing activities totaled $9.2 million during the year ended December 31, 2023, driven by payments totaling $9.1 million related to our former loan and security agreement with Oxford Finance LLC and SVB, or Loan Agreement, and $0.3 million in stock repurchases, offset by $0.2 million of cash received from employee stock purchases related to our Employee Stock Purchase Plan.

On May 25, 2023, we terminated our Loan Agreement and prepaid in full all outstanding amounts. The total payments made in the year ended December 31, 2023 were $9.1 million, comprised of (i) principal amounts outstanding as of December 31, 2022, totaling $8.6 million, (ii) a prepayment fee of approximately $62,000, and (iii) a final payment fee of approximately $0.5 million. As of December 31, 2023, we had no further obligations under the Loan Agreement.

Net cash used in financing activities totaled $1.2 million during the year ended December 31, 2022. We began making principal payments on our outstanding notes payable starting in October 2022 which totaled $1.4 million. These payments were offset by $0.2 million of cash received from employee stock purchases related to our Employee Stock Purchase Plan.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, and similarly did not and do not have any holdings in variable interest entities. We do have certain contingent consideration liabilities in the form of potential milestone payments that are included in our Biocon License and in our merger agreement with Bioniz which are not reflected in our balance sheet. However, based on our current operating plans and our assessment of the probability and potential timing of such payments, we believe those payments, if any, are remote and highly unlikely to come due within the next 12 months.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. We evaluate these estimates on an ongoing basis. We base our estimates on historical experience, known trends and events, financial models and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

We recognize revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration we are entitled to receive in exchange for such product or service. In doing so, we follow a five-step approach: (1) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. We consider the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. We apply the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with us, where the purpose of the contract is to obtain a product or a service that is an output of our ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that we will collect substantially all of the consideration to which we are entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. We identify each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) our promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable form other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration we are entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, we consider the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, we must estimate the consideration we expect to receive and use that amount as the basis for recognizing

revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the most likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, we allocate the transaction price to each distinct performance obligation in an amount that reflects the consideration we are entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) we transfer control of the product or the service applicable to such performance obligation.

In those instances where we first receive consideration in advance of satisfying its performance obligation, we classify such consideration as deferred revenue until (or as) we satisfy such performance obligation. In those instances where we first satisfy our performance obligation prior to our receipt of consideration, the consideration is recorded as accounts receivable.

We expense incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Accrued Research and Development Expense

We are required to estimate our expenses resulting from our obligations under contracts with vendors, consultants and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the preclinical study or clinical study as measured by the timing of various aspects of the study or related activities. We determine accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study or clinical study, we adjust our rate of expense recognition if actual results differ from our estimates.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-based Compensation Expense

We measure employee and non-employee stock-based awards, including stock options and stock purchase rights, at grant-date fair value and record compensation expense on a straight-line basis over the vesting period of the award. We use the Black-Scholes option pricing model to value our stock option awards. Estimating the fair value of stock option awards requires management to apply judgment and make estimates of certain assumptions, including the volatility of our common stock, the expected term of our stock options and the expected dividend yield on the measurement date. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. We record a full valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

We record uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. We will recognize interest and penalties in income tax expense if and when incurred.

Recent Accounting Pronouncements

See Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information concerning recent accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data required by this item are included after the signature page of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2023, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer, principal financial officer and principal accounting officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2023, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework (2013 Framework).* Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Trading Arrangements

During the three-months ended December 31, 2023, one of our executive officers adopted a trading plan for the orderly disposition of our securities set forth in the table below:

Name and Position	Action	Adoption/Termination Date	Type of Trading Arrangement		Total Shares of Common Stock to be Sold	Expiration Date
			Rule 10b5-1[1]	Non-Rule 10b5-1[2]		
Christine Zedelmayer, Chief Operating Officer	Adoption	December 12, 2023	X		322,823	December 12, 2024

[1] Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.
[2] " No n-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this item will be contained in our definitive proxy statement, or the Proxy Statement, to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2023, under the sections entitled “Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” “Information Regarding Committees of the Board of Directors,” “Executive Officers” and “Delinquent Section 16(a) Reports” and is incorporated in this Annual Report on Form 10-K by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Business Conduct and Ethics is available on our website at *www.equilliumbio.com.* The information on our website is not incorporated by reference into this Annual Report on Form 10-K. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website or in a Current Report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item will be contained in the Proxy Statement under the section entitled “Executive and Director Compensation” and is incorporated in this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be contained in the Proxy Statement under the sections entitled “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under Equity Compensation Plans” and is incorporated in this Annual Report on Form 10-K by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be contained in the Proxy Statement under the sections entitled “Transactions with Related Persons and Indemnification” and “Information Regarding the Board of Directors and Corporate Governance” and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be contained in the Proxy Statement under the section entitled “Principal Accountant Fees and Services” and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Consolidated Financial statements:

The Consolidated Financial Statements of Equillium, Inc. and Report of Independent Registered Public Accounting Firm are included after the Signatures page of this Annual Report on Form 10-K beginning on page F-1.

(a)(2) Financial Statement Schedules:

These schedules have been omitted because the required information is included in the financial statements or notes thereto or because they are not applicable or not required.

(a)(3) Exhibits

Exhibit Index

Exhibit Number	Description
2.1††*	Agreement and Plan of Merger, dated February 14, 2022, by and among Registrant, Bioniz Therapeutics, Inc., Project JetFuel Merger Sub, Inc. and Kevin Green, solely in his capacity as Securityholders' Representative, incorporated by reference by Exhibit 2.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 16, 2022.
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on October 16, 2018.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 16, 2018.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
4.2	Warrant to Purchase Common Stock, dated September 30, 2019, issued to Oxford Valley Finance LLC, incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2019.
4.3	Warrant to Purchase Common Stock, dated September 30, 2019, issued to Silicon Valley Bank, incorporated by reference to Exhibit 4.3 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2019.
4.4	Description of Common Stock, incorporated by reference to Exhibit 4.4 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
4.5	Form of Warrant, issued February 5, 2021, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 4, 2021.
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
10.2+	Equillium, Inc. 2017 Equity Incentive Plan and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
10.3+	Equillium 2018 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder, incorporated by reference to Exhibit 99.2 of the Registrant's Registration Statement on Form S-8 (File No. 333-227859) filed with the Securities and Exchange Commission on October 16, 2018.
10.4+	Equillium, Inc. 2018 Employee Stock Purchase Plan, incorporated by reference to Exhibit 99.3 of the Registrant's Registration Statement on Form S-8 (File No. 333-227859) filed with the Securities and Exchange Commission on October 16, 2018.
10.5†	Collaboration and License Agreement, dated May 22, 2017, by and between the Registrant and Biocon SA (which was subsequently assigned to Biocon Limited effective March 2018), incorporated by reference to

	Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2023.
10.6†	Clinical Supply Agreement, dated May 22, 2017, by and between the Registrant and Biocon SA (which was subsequently assigned to Biocon Limited effective March 2018), incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2023.
10.7	Standard Office Lease, effective as of February 1, 2018, by and between the Registrant and La Jolla Shores Plaza, LLC, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
10.8+	Offer Letter, dated June 1, 2018, by and between the Registrant and Daniel M. Bradbury, incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
10.9+	Offer Letter, dated March 19, 2018, by and between the Registrant and Jason A. Keyes, incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
10.10+	Offer Letter, dated June 1, 2018, by and between the Registrant and Bruce D. Steel, incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
10.11+	Amended and Restated Offer Letter, dated June 7, 2018, by and between the Registrant and Stephen Connelly, Ph.D., incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
10.12	First Amendment to Collaboration and License Agreement, effective as of September 28, 2018, by and between the Registrant and Biocon Limited, incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on October 2, 2018.
10.13	Second Amendment to Collaboration and License Agreement dated April 22, 2019, by and between the Registrant and Biocon Limited, incorporated by reference to Exhibit 10.15 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
10.14††	Third Amendment to Collaboration and License Agreement, dated December 10, 2019, by and between the Registrant and Biocon Limited, incorporated by reference to Exhibit 10.18 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
10.15+	Offer Letter, dated January 19, 2018, by and between the Registrant and Christine Zedelmayer, incorporated by reference to Exhibit 10.19 of the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2020.
10.16+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Daniel M. Bradbury, incorporated by reference to Exhibit 10.20 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
10.17+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Bruce D. Steel, incorporated by reference to Exhibit 10.22 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
10.18+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Christine Zedelmayer, incorporated by reference to Exhibit 10.23 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
10.19	Open Market Sale Agreement, dated as of October 5, 2023, by and between the Registrant and Jefferies LLC, incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 5, 2023.

10.20+	Equillium, Inc. Non-Employee Director Compensation Policy, as amended, incorporated by reference to Exhibit 10.25 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 23, 2022.
10.21	Fourth Amendment to Collaboration and License Agreement by and between Registrant and Biocon Limited, dated April 14, 2021, incorporated by referenced to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 13, 2021.
10.22	Fifth Amendment to Collaboration and License Agreement by and between Registrant and Biocon Limited, dated November 18, 2022, incorporated by reference to Exhibit 10.29 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 23, 2023.
10.23††	Asset Purchase Agreement, dated December 5, 2022, by and between the Registrant and Ono Pharmaceutical Co., Ltd, incorporated by reference to Exhibit 10.31 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 23, 2023.
10.24+	Equillium, Inc. 2024 Inducement Plan and Forms of Stock Option Grant Notice, Option Agreement, and Notice of Exercise thereunder, incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 8, 2024.
21.1	Subsidiaries of Equillium, Inc.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Securities Exchange Act, as amended, and 18 U.S.C. Section 1350.
97.1	Incentive Compensation Recoupment Policy.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Schedules and exhibits to the agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
** This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

†† Certain information in this exhibit has been omitted pursuant to Item 601 of Regulation S-K.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized**.**

EQUILLIUM, INC.

Date: March 25, 2024

By: /s/ Bruce D. Steel

Bruce D. Steel
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bruce D. Steel and Jason A. Keyes, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Bruce D. Steel Bruce D. Steel	President and Chief Executive Officer *(Principal Executive Officer)*	March 25, 2024
/s/ Jason A. Keyes Jason A. Keyes	Chief Financial Officer *(Principal Financial Officer)*	March 25, 2024
/s/ Penny Tom Penny Tom	Senior Vice President, Finance *(Principal Accounting Officer)*	March 25, 2024
/s/ Daniel M. Bradbury Daniel M. Bradbury	Chairman of the Board of Directors	March 25, 2024
/s/ Stephen Connelly, Ph.D. Stephen Connelly, Ph.D.	Member of the Board of Directors	March 25, 2024
/s/ Martha J. Demski Martha J. Demski	Member of the Board of Directors	March 25, 2024
/s/ Bala S. Manian, Ph.D. Bala S. Manian, Ph.D.	Member of the Board of Directors	March 25, 2024
/s/ Charles McDermott Charles McDermott	Member of the Board of Directors	March 25, 2024
/s/ Mark Pruzanski, M.D. Mark Pruzanski, M.D.	Member of the Board of Directors	March 25, 2024
/s/ Barbara Troupin, M.D. Barbara Troupin, M.D.	Member of the Board of Directors	March 25, 2024
/s/Y. Katherine Xu, Ph.D Y. Katherine Xu, Ph.D	Member of the Board of Directors	March 25, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
EQUILLIUM, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Equillium, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Equillium, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ KPMG LLP

We have served as the Company's auditor since 2018.

San Diego, California
March 25, 2024

Equillium, Inc.
Consolidated Balance Sheets
(In thousands, except share and par value data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 23,216	$ 59,107
Short-term investments	17,650	11,916
Accounts receivable	3,735	2,838
Prepaid expenses and other current assets	4,748	2,874
Total current assets	49,349	76,735
Operating lease right-of-use assets	796	1,191
Property and equipment, net	315	391
Other assets	70	104
Total assets	$ 50,530	$ 78,421
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,707	$ 3,977
Accrued expenses	6,697	7,239
Current portion of deferred revenue	15,729	14,700
Current portion of notes payable	-	5,714
Current portion of operating lease liabilities	440	408
Total current liabilities	27,573	32,038
Long-term notes payable	-	3,239
Long-term deferred revenue	-	10,378

Long-term operating lease liabilities	384	824
Total liabilities	27,957	46,479
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2023 and 2022; 35,254,752 and 34,414,149 shares issued and outstanding as of December 31, 2023 and 2022, respectively	3	3
Additional paid-in capital	208,170	204,268
Accumulated other comprehensive income	140	76
Accumulated deficit	(185,740)	(172,405)
Total stockholders' equity	22,573	31,942
Total liabilities and stockholders' equity	$ 50,530	$ 78,421

See accompanying notes.

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

	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenue	$ 36,084	$ 15,759
Operating expenses:		
Research and development	37,039	37,547
Acquired in-process research and development	-	23,049
General and administrative	13,567	17,239
Total operating expenses	50,606	77,835
Loss from operations	(14,522)	(62,076)
Other income (expense), net:		
Interest expense	(491)	(1,053)
Interest income	2,334	420
Other (expense) income, net	(76)	281
Total other income (expense), net	1,767	(352)
Net loss before income tax expense	(12,755)	(62,428)
Income tax expense	580	-
Net loss	$ (13,335)	$ (62,428)
Other comprehensive income, net:		
Unrealized gain (loss) on available-for-sale securities, net	108	(38)
Foreign currency translation (loss) gain	(44)	252
Total other comprehensive income, net	64	214
Comprehensive loss	$ (13,271)	$ (62,214)

	(	(
	0.38	1.85
Net loss per share, basic and diluted	$)	$)
	34,726,384	33,727,945
Weighted-average number of common shares outstanding, basic and diluted		

See accompanying notes.

Equillium, Inc.
Consolidated Statements of Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Capital	(Loss)	Deficit	Equity
Balance at December 31, 2021	29,455,668	$ 2	$ 176,618	$ (138)	$ (109,977)	$ 66,505
Issuance of common stock for Bioniz acquisition	4,820,230	1	22,541	-	-	22,542
Issuance of common stock under employee stock purchase plan	138,251	-	215	-	-	215
Vesting of restricted stock liability	-	-	53	-	-	53
Stock-based compensation expense	-	-	4,841	-	-	4,841
Comprehensive income	-	-	-	214	-	214
Net loss	-	-	-	-	(62,428)	(62,428)
Balance at December 31, 2022	34,414,149	$ 3	$ 204,268	$ 76	$ (172,405)	$ 31,942
Issuance of common stock for Bioniz acquisition	849,133	-	-	-	-	-
Issuance of common stock under employee stock purchase plan	289,855	-	165	-	-	165
Common stock repurchased	(298,385)	-	(260)	-	-	(260)
Stock-based compensation expense	-	-	3,997	-	-	3,997
Comprehensive income	-	-	-	64	-	64
Net loss	-	-	-	-	(13,335)	(13,335)

Balance at December 31, 2023	35,254,752	$ 3	$ 208,170	$ 140	$ (185,740)	$ 22,573

See accompanying notes.

Equillium, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating activities:		
Net loss	$ (13,335)	$ (62,428)
Adjustments to reconcile net loss to cash used in operating activities:		
Acquired in-process research and development	-	23,049
Depreciation	126	118
Stock-based compensation	3,997	4,841
Net unrealized loss on foreign currency transactions	58	260
Amortization of term loan discount and issuance costs	180	203
Amortization of premium and accretion of discounts on investments	(914)	127
Deferred revenue	(9,349)	25,078
Changes in operating assets and liabilities:		
Accounts receivable	(897)	(2,838)
Prepaid expenses and other current assets	(1,805)	(158)
Accounts payable	723	2,508
Accrued expenses	(554)	432
Right-of-use assets and lease liabilities, net	(13)	75
Net cash used in operating activities	(21,783)	(8,733)
Investing activities:		
Purchases of property and equipment	(50)	(279)
Purchases of short-term investments	(54,712)	(14,962)
Maturities of short-term investments	50,000	33,225

Cash acquired in Bioniz acquisition	-	700
Net cash (used in) provided by investing activities	(4,762)	18,684
Financing activities:		
Repayment of notes payable	(9,133)	(1,429)
Common stock repurchased	(260)	-
Proceeds from issuance of common stock under employee stock purchase plan	165	214
Net cash used in financing activities	(9,228)	(1,215)
Effect of exchange rate changes on cash and cash equivalents	(118)	5
Net (decrease) increase in cash and cash equivalents	(35,891)	8,741
Cash and cash equivalents at beginning of period	59,107	50,366
Cash and cash equivalents at end of period	$ 23,216	$ 59,107
Supplemental cash flow information:		
Cash paid for interest	$ 946	$ 847
Cash paid for income taxes	$ 580	$ -
Fair value of Bioniz assets acquired	$ -	$ 23,049
Issuance of common stock for Bioniz acquisition	-	(22,542)
Bioniz net liabilities assumed	$ -	$ 507

See accompanying notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Accounting Pronouncements

Description of Business

Equillium, Inc. (the Company) was incorporated in the state of Delaware on March 16, 2017 . The Company is a clinical-stage biotechnology company leveraging a deep understanding of immunobiology to develop novel therapeutics to treat severe autoimmune and inflammatory (immuno-inflammatory) disorders. The Company's strategy is focused on advancing the clinical development of its product candidates, including potentially pursuing additional indications and acquiring new product candidates and platforms to expand its pipeline. The Company intends to commercialize its product candidates either independently or through partnerships or otherwise monetize its pipeline through strategic transactions.

The Company's current clinical-stage product candidates consist of EQ101 and itolizumab (EQ001). EQ101 is a first in-class, selective, tri-specific synthetic peptide engineered to specifically inhibit IL-2, IL-9 and IL-15, key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immuno-inflammatory indications. Itolizumab (EQ001) is a first-in-class monoclonal antibody that selectively targets the immune checkpoint receptor CD6, which plays a central role in the modulation of effector T cell (T_{eff} cell) activity and trafficking that drives a number of immuno-inflammatory diseases across multiple therapeutic areas. The Company is also engaged in the discovery and optimization of additional peptide-based product candidates that selectively target multiple cytokines and is currently advancing the preclinical development of EQ302, a potential first-in-class, orally delivered, bi-specific inhibitor of IL-15 and IL-21. The Company is focused on developing EQ101, EQ302 and itolizumab (EQ001) as potential best-in-class, disease modifying treatments for multiple severe immuno-inflammatory disorders.

From inception through December 31, 2023, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing rights to itolizumab (EQ001), conducting non-clinical research, filing three Investigational New Drug applications (INDs), conducting clinical development of the Company's product candidates, conducting business development activities such as the acquisition of Bioniz Therapeutics, Inc. (Bioniz), the Asset Purchase Agreement with Ono Pharmaceutical Co., Ltd. (Ono) and other transactions not completed, initiating a stock repurchase program, and the general and administrative activities associated with operating a public company. In addition, the Company has not generated revenues from product sales, milestone payments, or royalties, and the sales and income potential of its business is unproven.

Liquidity and Business Risks

As of December 31, 2023, the Company had $

40.9

million in cash, cash equivalents and short-term investments. The Company has incurred significant operating losses and negative cash flows from operations. The Company expects to use its cash, cash equivalents, and short-term investments primarily for clinical development, non-clinical research, manufacturing and product supply, potential acquisition of new products, potential repurchases of shares of its common stock under its stock repurchase program, legal and other regulatory compliance, employee compensation and related expenses, insurance premiums, working capital and other general overhead costs. The Company does not expect to generate any revenues from product sales unless and until the Company successfully completes development and obtains regulatory approval of any of its product candidates, which is unlikely to happen within the next 12 months, if ever. Accordingly, until such time as the Company can generate significant revenue from sales of its product candidates, if ever, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements, such as its Asset Purchase Agreement with Ono. However, the Company may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. As a result of the conflict between Russia and Ukraine, the conflict in the Middle East, bank failures, inflationary pressures on the economy and monetary policy responses taken by government agencies and other macroeconomic factors, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. The Company's failure to raise capital or enter into such other arrangements when needed would have a negative impact on the Company's financial condition and could force the Company to delay, reduce or terminate its research and development programs or other operations, or grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market itself. Management believes that the Company's cash, cash equivalents and short-term investments as of December

31, 2023, will be sufficient to fund operations for at least the next 12 months from the date this Annual Report on Form 10-K is filed with the Securities and Exchange Commission (SEC).

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and the rules and regulations of the SEC. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) promulgated by the Financial Accounting Standards Board (FASB).

Certain reclassifications have been made to prior-year amounts to conform to the current period presentation.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency Translation

The Company's wholly-owned subsidiary in Australia uses its local currency as its functional currency. Assets and liabilities are translated into U.S. dollars at quarter-end exchange rates and revenues and expenses are translated at average exchange rates during the year-to-date periods. Foreign currency translation adjustments for the reported periods are included in accumulated other comprehensive income in the Company's consolidated statements of comprehensive loss, and the cumulative effect is included in the stockholders' equity section of the Company's consolidated balance sheets.

Recently Issued and Recently Adopted Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires an acquirer to recognize and measure contract assets and liabilities acquired in a business combination in accordance with Revenue from Contracts with Customers (Topic 606) rather than adjust them to fair value at the acquisition date. This accounting standards update will be effective for the Company beginning in the first quarter of fiscal 2024. The Company does not expect this accounting standards update to have a material impact on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 requires annual disclosures of specific categories in the rate reconciliation, additional information for reconciling items that meet a quantitative threshold and a disaggregation of income taxes paid, net of refunds. ASU 2023-09 also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities. ASU 2023-09 is effective for the Company beginning with the Company's Annual Report on Form 10-K for the year ending December 31, 2025. Early adoption is permitted. ASU 2023-09 should be applied prospectively. Retrospective adoption is permitted. The Company is currently assessing the impact this standard will have on the Company's consolidated financial statements.

No other new accounting pronouncements or legislation issued or effective as of December 31, 2023 have had, or are expected to have, a material impact on our consolidated financial statements.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Significant estimates in the Company's consolidated financial statements relate to accrued research and development expense, revenue recognition and the valuation of equity awards. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in

excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company's investment policy includes guidelines for the quality of the related institutions and financial instruments and defines allowable investments that the Company may invest in, which the Company believes minimizes the exposure to concentration of credit risk.

Comprehensive Income (Loss)

The Company is required to report all components of comprehensive loss, including net loss, in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation gains and losses. Other comprehensive income, net includes unrealized gains or losses on short-term investments as well as foreign currency translation gains or losses.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking and savings accounts, and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. At December 31, 2023 and 2022, the Company's cash and cash equivalents were primarily comprised of money market funds.

Short-Term Investments

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive loss. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Accounts Receivable

Accounts receivable includes trade accounts receivables from the Ono Asset Purchase Agreement (see Note 9). Reimbursable costs that have not been invoiced as of the balance sheet date are recorded as unbilled accounts receivable. As of December 31, 2023, and 2022, the Company had unbilled accounts receivable totaling $

3.7
million and $

2.8
million, respectively, classified as accounts receivable on its consolidated balance sheet. The Company makes judgments as to its ability to collect outstanding receivables and provide an allowance for receivables when collection becomes doubtful. Allowance for credit risk for accounts receivable is established based on various factors including credit profiles of the Company's customers, historical payments and current economic trends. The Company reviews its allowance for accounts receivable by assessing individual accounts receivable over a specific aging and amount. The estimate of expected credit losses is based on information about past events, current economic conditions, and forecasts of future economic conditions that affect the collectability. Accounts receivable is written-off on a case-by-case basis, net of any amounts that may be collected. As of each of December 31, 2023, and 2022,

no

credit losses have been recorded by the Company.

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Australian research and development tax incentive	$ 2,054	$ 1,006
Prepaid clinical development	1,008	449
Prepaid insurance	532	709
Other receivables	497	269
Prepaid other	422	433

Other current assets	235	8
Total prepaid expenses and other current assets	$ 4,748	$ 2,874

Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to five years).

Leases

The Company determines if an arrangement is a lease at inception. Lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. For operating leases with an initial term greater than 12 months, the Company recognizes operating lease right-of-use assets and operating lease liabilities based on the present value of lease payments over the lease term at the commencement date. Operating lease right-of-use assets are comprised of the lease liability plus any lease payments made and excludes lease incentives. Lease terms include options to renew or terminate the lease when the Company is reasonably certain that the renewal option will be exercised or when it is reasonably certain that the termination option will not be exercised. For the Company's operating leases, if the interest rate used to determine the present value of future lease payments is not readily determinable, the Company estimates its incremental borrowing rate as the discount rate for the lease. The Company's incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, and in similar economic environments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has elected the practical expedient to not separate lease and non-lease components.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company’s current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since inception.

Accrued Research and Development Expense

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects research and development expenses in its consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities. The Company determines accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and development personnel as to the progress of studies, or other services being conducted. During the course of a study, the Company adjusts its rate of expense recognition if actual results differ from its estimates. The Company classifies its estimates for accrued research and development expenses as accrued expenses on the accompanying consolidated balance sheet.

Australian Research and Development Tax Incentive

The Company is eligible under the Australian Research and Development Tax Incentive Program, or the Tax Incentive, to obtain a cash refund from the Australian Taxation Office for eligible research and development expenditures. To be eligible, the filing entity must have revenue of less than AUD $

20.0
million during the reimbursable period and cannot be controlled by income tax exempt entities. The Tax Incentive is recognized as a reduction to research and development expense when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured. The Company classifies its estimate for the Tax Incentive as prepaid expenses and other current assets on the accompanying consolidated balance sheet. As of December 31, 2023 and 2022, the Company recorded $

2.1
million and $

1.0
million within prepaid expenses and other current assets attributed to the Tax Incentive, respectively.

Revenue Recognition

The Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance

obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. The Company applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Contract Assets

The Company does not have material amounts of contract assets since revenue is recognized as control of goods is transferred or as services are performed. There are a small number of research and development services that may occur over a period of time, but that period of time is generally very short in duration. Any contract assets that may arise are recorded in accounts receivable in the Company's consolidated balance sheet net of an allowance for credit losses. The Company's contract assets includes trade accounts receivables from the Ono Asset Purchase Agreement (see Note 9). Reimbursable costs that have not been invoiced as of the balance sheet date are recorded as unbilled accounts receivable. As of December 31, 2023 and 2022, the Company had unbilled accounts receivable totaling $

3.7
million and $

2.8
million, respectively, classified as accounts receivable on its consolidated balance sheet.

Contract Liabilities

The Company's contract liabilities consist of advance payments and deferred revenue. The Company classifies advance payments and deferred revenue as current or noncurrent based on the timing of when it expects to recognize revenue. Generally, all contract liabilities are expected to be recognized within one year and are included in deferred revenue in the Company's consolidated balance sheet. The noncurrent portion of deferred revenue is included and separately disclosed in the Company's consolidated balance sheet.

Acquired In-Process Research and Development Expense

The Company has acquired, and may continue to acquire, the rights to develop new product candidates. Payments to acquire a new product candidate, as well as future milestone payments associated with asset acquisitions in which contingent payments are resolved are immediately expensed as acquired in-process research and development provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Research and Development

Research and development expenses include salaries and related overhead expenses, non-cash stock-based compensation expense, external research and development expenses incurred under arrangements with third parties, costs of services performed by consultants and contract research organizations, and regulatory costs including those related to preparing and filing INDs with the FDA. Research and development costs are expensed as incurred.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the consolidated statement of operations.

Stock-based Compensation

The Company measures employee and nonemployee stock-based awards, including stock options and purchase rights, at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. The Company uses the Black-Scholes option pricing model to value its stock option awards. Estimating the fair value of stock option awards requires management to apply judgment and make estimates of certain assumptions, including the volatility of the Company's common stock, the expected term of the Company's stock options, the expected dividend yield and the fair value of the Company's common stock on the measurement date. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

Pursuant to the Internal Revenue Code of 1986, as amended (IRC), specifically Sections 382 and 383, the Company's ability to use tax attribute carryforwards to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than

50

% within a three-year testing period. The Company completed an ownership change analysis through June 30, 2023 pursuant to IRC Section 382 and determined that the Company's ability to offset taxable income in 2023 is not expected to be impacted by ownership changes occurring prior to that date. If ownership changes within the meaning of IRC Section 382 occur in the future, the amount of remaining tax attribute carryforwards available to offset future

taxable income and income tax expense in future years may be significantly restricted or eliminated, including those acquired through Bioniz. Further, the Company's deferred tax assets associated with such tax attributes could be significantly reduced or eliminated upon realization of an ownership change within the meaning of IRC Section 382. If eliminated, the related asset would be removed from the deferred tax asset schedule, with a corresponding reduction in the valuation allowance. Additionally, limitations on the utilization of the Company's tax attribute carryforwards can increase the amount of taxable income and current income tax expense recognized. Due to the existence of the valuation allowance, ownership change limitations that are not significant may not impact the Company's effective tax rate.

The Tax Cuts and Jobs Act of 2017 amended IRC Section 174 to eliminate the immediate expensing of research and experimental (R&E) expenditures for amounts paid or incurred in tax years beginning after December 31, 2021. The rules of IRC Section 174, as amended, require taxpayers to charge their R&E expenditures and software development costs (collectively, R&E expenditures) to a capital account. Capitalized costs are required to be amortized over five or fifteen years for research performed within the United States or foreign jurisdictions, respectively.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more- likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than

50

percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company’s potentially dilutive securities include outstanding options under the Company’s equity incentive plan and outstanding warrants to purchase common stock, each of which have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company’s net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Year Ended December 31,	
	2023	2022
Common stock options	7,031,075	5,102,501
Common stock warrants	1,366,141	1,366,141
Total	8,397,216	6,468,642

3. Fair Value of Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and short-term investments. Cash equivalents consisted of money market funds and short-term investments consisted of U.S. treasury securities and certificates of deposit. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bid and/or offers.

The following tables summarize the Company's assets that require fair value measurements on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

		Fair Value Measurements Using		
	December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments:				
U.S. treasury securities	$ 17,650	$ 17,650	$ -	$ -
Total	$ 17,650	$ 17,650	$ -	$ -

		Fair Value Measurements Using		
	December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments:				
U.S. treasury securities	$ 11,916	$ 11,916	$ -	$ -
Total	$ 11,916	$ 11,916	$ -	$ -

U.S. treasury securities and certificates of deposit are valued using Level 1 inputs. Level 1 securities are valued at unadjusted quoted prices in active markets that are observable at the measurement date for identical, unrestricted assets or liabilities. Fair values determined by Level 2 inputs, which utilize data points that are observable such as quoted prices, interest rates and yield curves, require the exercise of judgment and use of estimates, that if changed, could significantly affect the Company's financial position and results of operations. Investments in agency securities are valued using Level 2 inputs. Level 2 securities are initially valued at the transaction price and subsequently valued and reported utilizing inputs other than quoted prices that are observable either directly or indirectly, such as quotes from third-party pricing vendors.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued liabilities, approximate their fair value due to their short maturities. At December 31, 2022, the carrying amount of the Company's notes payable was $

9.0

million, which approximated their fair value as the terms of the notes are consistent with the market terms of transactions with similar profiles (Level 2 inputs). The notes payable were paid off during 2023 and were no longer outstanding as of December 31, 2023. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

The Company did

no

t hold any Level 1, 2 or 3 financial liabilities that are recorded at fair value on a recurring basis as of December 31, 2023 or 2022.

4. Short-term Investments

The following table summarizes the Company's short-term investments (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2023					
U.S. treasury securities	1 or less	$ 17,632	$ 18	$ -	$ 17,650
Total		$ 17,632	$ 18	$ -	$ 17,650
December 31, 2022					
U.S. treasury securities	1 or less	$ 12,006	$ -	$ (90)	$ 11,916
Total		$ 12,006	$ -	$ (90)	$ 11,916

All of the Company's available-for-sale securities are available to the Company for use in its current operations. As a result, the Company categorizes all of these securities as current assets even though the stated maturity of some individual securities may be one year or more beyond the balance sheet date. All of the Company's securities have a maturity within two years of the balance sheet date.

There were

no

impairments considered other-than-temporary during the periods presented, as it is management's intention and ability to hold the securities until a recovery of the cost basis or recovery of fair value. Unrealized gains and losses are included in accumulated other comprehensive income (loss).

5. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31, 2023	2022
Furniture & fixtures	$ 60	$ 60
Machinery & lab equipment	584	534
Computer equipment	15	26
Leasehold improvements	20	20
Less accumulated depreciation and amortization	(364)	(249)
Property and equipment, net	$ 315	$ 391

Depreciation expense related to property and equipment was approximately $

126,000
and $

118,000
for the years ended December 31, 2023 and 2022, respectively. During the year ended December 31, 2023 and 2022, the Company disposed of fully depreciated property and equipment totaling approximately $

11,000
and $

16,000
, respectively.

No

material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2023 or 2022.

6. Acquisition

On February 14, 2022, the Company entered into an Agreement and Plan of Merger with Project JetFuel Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company (Merger Sub), Bioniz and Kevin Green, solely in his capacity as representative of the securityholders of Bioniz (the Securityholders' Representative). As consideration for the acquisition of Bioniz, the Company agreed to (a) issue up to an aggregate of

5,699,492
shares of the Company's common stock (Merger Shares), and (b) make contingent payments up to an aggregate of $

57.5
million based on the achievement of certain regulatory events for the Bioniz product candidates commencing on first U.S. approval, and up to an aggregate of $

250
million based on the achievement of certain commercialization events for product candidate BNZ-1 (now referred to as EQ101) as set forth in the Merger Agreement. The Merger Shares may be adjusted downward after the closing, pursuant to procedures set forth in the Merger Agreement, including with respect to indemnification claims and in connection with the finalization of transaction expenses, debt, net exercise taxes and working capital amounts at closing.

At the closing, the Company delivered to the transfer agent

4,820,230
shares of its common stock for issuance to former stockholders of Bioniz per the terms of the Merger Agreement. Up to an additional

879,252
shares of the Company's common stock, pending any adjustments per the terms of the Merger Agreement, were to be issued to former stockholders of

Bioniz 18 months after closing. On August 14, 2023, the Company issued

849,133

shares of the Company's common stock to the former stockholders of Bioniz, net of final adjustments per the terms of the Merger Agreement. The fair value of the fewer shares issued was not deemed material and, therefore, there was

no

adjustment to in-process research and development recorded on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023, or to additional paid-in capital on the consolidated balance sheet as of December 31, 2023. The acquisition of Bioniz expanded the Company's pipeline of novel immunomodulatory drug candidates, adding a first-in-class clinical stage asset, BNZ-1, now referred to as EQ101, and a proprietary product discovery platform.

The Company determined the acquisition constituted an acquisition of assets instead of a business combination as substantially all of the fair value of the gross assets acquired was concentrated in a group of similar identifiable assets, and therefore, the acquisition was not considered a business. As the Company is recording the transaction as an asset acquisition under ASC 805, the contingent payments will be recognized upon achievement and at that time will be expensed to in-process research and development. Transaction costs of approximately $

0.4

million associated with the acquisition were included in the Company's research and development expense during the year ended December 31, 2022.

A summary of the purchase price allocation is as follows (in thousands):

	Amount
Assets acquired:	
Cash	$ 700
Prepaid expenses and other current assets	28
Fixed assets	6
Total assets acquired	734
Liabilities assumed:	
Accounts payable	265
Accrued expenses	976
Total liabilities assumed	1,241
Net liabilities acquired	$ 507
Issuance of common stock for Bioniz acquisition	22,542
Acquired in-process research and development	$ 23,049

7. Leases

The Company's leases relate primarily to office and laboratory facilities located in La Jolla, California and previously in South San Francisco, California. The Company's lease of office space in South San Francisco expired in February 2023 and the Company did not renew that lease. The Company's lease of laboratory space in La Jolla expires in 2025 , and the Company's leases of office space in La Jolla expire in 2027 . The terms of the Company's non-cancelable operating lease arrangements typically contain fixed lease payments which increase over the term of the lease at fixed rates and include rent holidays and provide for additional renewal periods. Lease expense is recognized over the term of the lease on a straight-line basis. All of the Company's leases are classified as operating leases. The Company has determined that periods covered by options to extend the Company's leases are excluded from the lease term as the Company is not reasonably certain the Company will exercise such options. Operating lease expense, including expenses related to short-term leases, were $

0.5

million and $

0.6
million for the years ended December 31, 2023 and 2022, respectively.

The Company records its right-of-use-assets within other assets (long term) and its operating lease liabilities within other current and long-term liabilities.

Additional information related to the Company's leases as of and for the year ended December 31, 2023, is as follows (in thousands, except lease term and discount rate):

	December 31, 2023
Balance sheet information	
Right-of-use assets	$ 796
Lease liabilities, current	$ 440
Lease liabilities, non-current	384
Total lease liabilities	$ 824
Other information	
Weighted average remaining lease term	2.28 years
Weighted average discount rate	8.25%
Supplemental cash flow information	
Operating cash outflows from operating leases	$ 499
Right-of-use assets obtained in exchange for lease obligations	$ —

Maturities of lease liabilities as of December 31, 2023, were as follows (in thousands):

Year ending December 31,	
2024	$ 492
2025	219
2026	169
2027	28
Total undiscounted lease payments	908
Less: imputed interest	(84)
Total lease liabilities	$ 824

As of December 31, 2023, the Company does not have any leases that have not yet commenced that create significant rights and obligations.

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2023	2022
Accrued payroll and other employee benefits	$ 3,054	$ 2,975
Clinical development	2,265	3,253
Non-clinical research	947	465
Other accruals	431	472
Accrued interest	-	74
Total accrued expenses	$ 6,697	$ 7,239

9. Partnerships

Asset Purchase Agreement with Ono Pharmaceutical Co., Ltd.

On December 5, 2022, the Company and Ono, a Japan kabushiki kaisha, entered into an Asset Purchase Agreement pursuant to which the Company granted Ono the exclusive right, but not the obligation, to acquire the Company's rights to itolizumab (the Option). These rights include all therapeutic indications and the rights to commercialize itolizumab in the United States, Canada, Australia, and New Zealand. In exchange for the Option, Ono paid the Company a one-time, upfront payment of an amount equal to JPY

3.5
billion, or $

26.4
million.

If Ono exercises the Option, Ono will pay the Company a one-time payment of an amount equal to JPY

5.0
billion, or approximately $

33.1
million based on the currency exchange rate quoted by MUFG Bank, Ltd. on March 21, 2024. The Company is also eligible to receive up to $

101.4
million upon the achievement of certain development and commercialization milestones.

The Company is responsible for conducting all research and development of itolizumab, which is being funded by Ono on a quarterly basis from July 1, 2022, through the option period. Unless terminated early, the option period will expire three months following the delivery of topline data from the EQUALISE clinical study in lupus nephritis and interim data from the EQUATOR Phase 3 clinical study in acute graft-versus-host disease.

The Asset Purchase Agreement can be terminated at any time by Ono upon written notice, provided that in limited circumstances Ono will be obligated to continue to reimburse the Company for research and development costs and expenses of itolizumab for a certain period of time following such termination. If Ono does not timely exercise its Option, the Asset Purchase Agreement and the Option will automatically terminate. The Asset Purchase Agreement also contains customary termination rights for both parties for material breach and an outside date (subject to limited adjustments) that permits either party to terminate the Asset Purchase Agreement if the closing has not occurred by December 31, 2025.

The Asset Purchase Agreement contains customary representations and warranties with respect to both the Company and Ono. Additionally, the Company is subject to customary obligations and covenants, including affirmative and negative operating covenants on the Company with respect to its business as it applies to the development and exploitation of itolizumab, exclusivity obligations that prohibit the Company, except in limited circumstances, including in connection with the sale of the Company, from pursuing a direct or indirect sale, license or other disposition of all or any portion of the Company's itolizumab program or any of the assets to be purchased pursuant to the Asset Purchase Agreement and indemnification obligations, which, except in limited circumstances, are subject to customary caps and deductibles.

The Company applied ASC 808, *Collaborative Arrangements,* to the Asset Purchase Agreement and determined that the agreement is applicable to such guidance. The Company concluded that Ono represented a customer and applied relevant guidance from ASC 606, *Revenue Recognition*, (ASC 606) to evaluate the appropriate accounting for the Asset Purchase Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of a license to Ono to certain of its intellectual property subject to certain conditions and the conduct of research and development services. The Company determined that its grant of a license to Ono to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research and development services. Accordingly, the Company determined that all performance obligations should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and development services.

The Company also assessed, in connection with the upfront and non-creditable payment of JPY

3.5
billion or $

25.8
million, invoiced on December 5, 2022, that there was not a significant financing component in the Asset Purchase Agreement. The Company received payment of $

26.4
million related to this upfront payment in December 2022 which included a foreign currency realized gain of $

0.6
million as the initial invoice for the upfront payment was denominated in JPY.

The Company also assessed the effects of any variable elements under the Asset Purchase Agreement. Such assessment evaluated, among other things, the likelihood of receiving (i) option fees and (ii) various clinical, regulatory and commercial milestone payments. Based on its assessment, the Company concluded that, based on the likelihood of these variable components occurring, there was not a significant variable element included in the transaction price. Accordingly, the Company has not assigned a transaction price to any option fees or milestone payments under the Asset Purchase Agreement given the substantial uncertainty related to their achievement.

In accordance with ASC 606, the Company determined that the initial transaction price under the Asset Purchase Agreement equals $

102.6
million, consisting of the upfront and non-creditable payment of $

25.8
million and the aggregate estimated research and development funding of $

76.8
million over the estimated option period. The upfront payment of $

25.8
million was recorded as deferred revenue and is being recognized as revenue over time in conjunction with the Company’s conduct of research and development services as the research and development services are the primary component of the combined performance obligations. Revenue associated with the upfront payment will be recognized based on actual costs incurred as a percentage of the estimated total costs expected to be incurred over the expected term of the research and development services. Reimbursable research and development costs will be recognized as revenue as incurred.

The Company recognized revenue of $

36.1
million and $

15.8
million under the Asset Purchase Agreement during the years ended December 31, 2023 and 2022, respectively. Such revenue was comprised of $

27.0
million associated with development funding and $

9.1
million associated with the amortization of the upfront payment during the year ended December 31, 2023. Such revenue was comprised of $

11.8
million associated with development funding and $

4.0
million associated with the amortization of the upfront payment during the year ended December 31, 2022. As of December 31, 2023, aggregate deferred revenue related to the Asset Purchase Agreement was $

15.7
million, which was all classified as current on the consolidated balance sheet.

As of December 31, 2023, the Company has received $

38.0
million in cash related to aggregate development funding payments from Ono.

Biocon Collaboration and License Agreement

In May 2017, the Company entered into a collaboration and license agreement (which was amended in September 2018, April 2019, December 2019, April 2021 and November 2022), clinical supply agreement, investor rights agreement, and common stock purchase agreement (collectively License Agreements) with Biocon SA (subsequently assigned to Biocon Limited, or together, Biocon). Pursuant to the License Agreements, Biocon granted the Company an exclusive license to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit itolizumab and any pharmaceutical composition or preparation containing or comprising itolizumab that uses Biocon technology or Biocon know-how (collectively a Biocon Product) in the United States, Canada, Australia and New Zealand (collectively Equillium Territory). The Company also has the right to sublicense through multiple tiers to third parties, provided such sublicenses comply with the terms of the License Agreements and the Company provides Biocon a copy of each sublicense agreement within 30 days of execution. If the Company grants a third party a sublicense of its rights to develop and commercialize Biocon Products in Australia or New Zealand, the Company will be required to pay Biocon a high double-digit percentage of any upfront payment the Company receives from such sublicensee for such sublicense, as well as a high double-digit percentage of any additional payments the Company receives from such sublicensee for such sublicense, including but not limited to royalty payments on net sales of Biocon Products by such sublicensee. Under the License Agreements, the Company granted back to Biocon a license to use its technology and know-how related to itolizumab and Biocon Products in certain countries outside of the Equillium Territory. Pursuant to the License Agreements, Biocon agreed to be the Company's exclusive supplier of itolizumab clinical drug product. Biocon will provide clinical drug product at no cost for up to three concurrent orphan indications until the Company’s first U.S. regulatory approval and all other clinical drug product at Biocon’s cost. In addition, the Company has agreed to co-fund an ongoing Phase 2 clinical study of itolizumab in subjects with ulcerative colitis being conducted by Biocon in India.

In consideration of the rights granted to the Company by Biocon, the Company issued Biocon a total of

2,316,134
shares of its common stock.

In addition, the Company is obligated to pay Biocon up to an aggregate of $

30
million in regulatory milestone payments upon the achievement of certain regulatory approvals and up to an aggregate of $

565
million in sales milestone payments upon the achievement of first commercial sale of product and specified levels of product sales. The Company is also required to pay royalties on tiers of aggregate annual net sales of Biocon Products by the Company, the Company's affiliates and the Company's sublicensees in the United States and Canada at percentages from the mid-single digits to sub-teen double-digits and on tiers of aggregate annual net sales of Biocon Products by the Company and the Company's affiliates (but not the Company's sublicensees) in Australia and New Zealand, in each case, subject to adjustments in certain circumstances. Biocon is also required to pay the Company royalties at comparable percentages for sales of itolizumab (EQ001) outside of the Equillium Territory if the approvals in such geographies included or referenced the Company’s data including data from certain of the Company’s clinical studies, subject to adjustments in certain circumstances. Should Ono exercise its option to acquire the Company's rights to itolizumab (EQ001), as described below, the aforementioned milestone payments and royalties potentially owed to Biocon would become Ono’s responsibility, and the potential royalties on sales of itolizumab outside of the Equillium Territory would be become Ono’s right. Under the License Agreements, net sales are calculated on a country-by-country basis and are subject to adjustments, including whether the Biocon Product is sold in the form of a combination product. As of December 31, 2023, the Company has not made or received payments in connection with the milestones or royalties within the agreement.

10. Notes Payable

On September 30, 2019 (the Effective Date), the Company entered into a Loan and Security Agreement (the Loan Agreement) with two lenders (the Lenders) pursuant to which the Company borrowed $

10.0
million from the Lenders (the Term Loan), which represents the maximum amount the Company is permitted to borrow under the terms of the Loan Agreement.

The Term Loan was set to mature on June 1, 2024 (the Maturity Date) and was initially being repaid through interest-only payments, which originally extended through June 30, 2021, followed by

36
equal monthly payments of principal and interest. The Term Loan interest was at a floating per annum rate equal to the greater of (i)

8.25
% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately preceded the month in which the interest was being accrued, plus (b)

3.00
%.

On April 23, 2021, the Loan Agreement was amended to (i) change the final payment percentage from

4.5
% to

5.0
% and (ii) extend the interest-only payment period based on achieving the following milestones: (a) the Company achieving positive data in the Company's Phase 1b aGVHD trial of itolizumab (EQ001) supporting a formal decision to advance into Phase 2 or Phase 3 development, and as confirmed by the Company's Board of Directors in written board minutes (the Interest-Only Extension Milestone) and (b) the Company initiating a pivotal Phase 3 aGVHD trial (the Interest-Only Extension II Milestone). In May 2021, the Company achieved the Interest-Only Extension Milestone, and in March 2022, the Company obtained confirmation from the Lenders that the Interest-Only Extension II Milestone had been achieved, which extended the interest-only payments through September 30, 2022, followed by

24
equal monthly principal payments and interest.

In February 2022, the Company entered into the Third Amendment to the Loan Agreement (the Third Amendment) which added Bioniz as a secured party to the loan.

Under the Loan Agreement, the Company was required to make a final payment of

5.00
% of the original principal amount of the Term Loan drawn payable on the earlier of (i) the Maturity Date, (ii) the acceleration of the Term Loan in the event of a default, or (iii) the prepayment of the Term Loan (the Final Payment). The Company could prepay all, but not less than all, of the Term Loan upon 30 days' advance written notice to the lender, provided that the Company was obligated to pay a prepayment fee equal to (i)

3.00
% of the principal amount of the Term Loan prepaid on or before the first anniversary of the applicable funding date, (ii)

2.00
% of the principal amount of the Term Loan prepaid between the first and second anniversary of the funding date, and (iii)

1.00
% of the principal amount of the Term Loan prepaid thereafter, and prior to the Maturity Date (each, a Prepayment Fee).

In connection with entering into the Loan Agreement, the Company issued to the Lenders warrants exercisable for

80,428
shares of the Company's common stock (the Warrants). The Warrants are exercisable in whole or in part, immediately, and have a per share exercise price of $

3.73
, which was the closing price of the Company's common stock reported on The Nasdaq Global Market (prior to the Company's transfer to The Nasdaq Capital Market on September 15, 2023) on the day prior to the Effective Date. The Warrants will terminate on the earlier of September 30, 2029, or the closing of certain merger or consolidation transactions.

On May 25, 2023, the Company prepaid in full all amounts due and owing under, and terminated, the Loan Agreement. In connection with the prepayment and termination of the Loan Agreement, the Company paid a total of approximately $

6.8
million, which consisted of (i) the remaining principal amount and interest outstanding of approximately $

6.2
million as of the date of the repayment, (ii) a Prepayment Fee of approximately $

62,000
, (iii) the Final Payment of approximately $

0.5
million, and (iv) the remainder for transaction expenses. As of December 31, 2023, the Company had

no
further obligations under the Loan Agreement.

The aggregate carrying amounts of the Term Loan is comprised of the following (in thousands):

	December 31,	
	2023	2022
Principal	$ -	$ 8,571
Add: accreted liability for final payment fee	-	430
Less: unamortized discount	-	(48)

Total	-	8,953
	$	$

11. Stockholders' Equity

As of December 31, 2023, the Company's authorized capital stock consisted of

200,000,000
shares of common stock, par value $

0.0001
per share, and

10,000,000
shares of preferred stock, par value $

0.0001
per share.

The Company had

35,254,752
and

34,414,149
shares of common stock outstanding as of December 31, 2023 and 2022, respectively.

2023 ATM Facility

In October 2023, we entered into an at-the-market facility with Jefferies LLC, or Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $

21.95
million from time to time through Jefferies acting as our sales agent, or the 2023 ATM Facility. As of the filing of this Annual Report on form 10-K, we have

no
t sold any shares under the 2023 ATM Facility.

Authorization of Stock Repurchase Program

In July 2023, the Company's board of directors authorized a stock repurchase program pursuant to which the Company may repurchase up to $

7.5

million of shares of its common stock through December 31, 2024. Under the program, the Company may repurchase shares of common stock during the term of the program through open market transactions or such other transactions as the Company's board of directors or designated committee thereof may approve from time to time. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of the Company's common stock, alternative investment opportunities, the Company's cash resources, restrictions under any of the Company's agreements, corporate and regulatory requirements and market conditions. As of December 31, 2023, the Company has repurchased

298,385

shares of its common stock under the stock repurchase program for a total of $

0.3

million. There have been no repurchases of the Company's common stock under the stock repurchase program since December 31, 2023 and through the date of the filing of this Annual Report on Form 10-K. The Company expects to fund any future repurchase of shares of its common stock, if any, under the program with existing cash and cash equivalents.

Repricing of Outstanding Options

On August 7, 2023, the Company's board of directors approved an option repricing, which was effective on August 14, 2023 (the Effective Date). The repricing applies to outstanding options to purchase shares of the Company's common stock that, as of the Effective Date, were held by the Company's employees, officers and certain non-employee directors (the Outstanding Options), to the extent such Outstanding Options have an exercise price in excess of the closing trading price of the Company's common stock on the Effective Date, and were granted under the Company's 2017 Equity Incentive Plan or 2018 Equity Incentive Plan (the 2018 Plan). As of the Effective Date,

6,628,589

of the Outstanding Options were repriced such that the exercise price per share for such Outstanding Options was reduced to the closing trading price of the Company's common stock on the Effective Date, except that a premium exercise price will apply for certain exercises, as further described below. The Outstanding Options that were repriced on the Effective Date (the Repriced Options) included the Outstanding Options held by the Company's executive officers and certain non-employee directors.

If a Repriced Option is exercised prior to the Retention Period End Date (as defined below), or the optionholder's employment or service terminates under certain circumstances prior to the Retention Period End Date, the optionholder will be required to pay a premium price equivalent to the original exercise price per share of the Repriced Options. The "Retention Period End Date" means the earliest of (i) the date 18 months following the Effective Date, (ii) a Change in Control (as defined in the 2018 Plan), and (iii) the optionholder's termination of Continuous Service (as defined in the 2018 Plan) as a result of death, disability or certain other not for Cause (as defined in the 2018 Plan) terminations.

In addition to the amendment to the exercise prices of the Repriced Options, any Repriced Options that were previously Incentive Stock Options were amended to become Nonstatutory Stock Options (each as defined in the 2018 Plan). There were

no

changes to the number of shares, the vesting schedule or the expiration date of the Repriced Options.

The effect of the repricing resulted in a total incremental non-cash stock-based compensation expense of $

1.3

million, which was calculated using the Black-Scholes option-pricing model, of which $

0.8

million of the incremental non-cash stock-based compensation expense is associated with vested Repriced Options and will be recognized on a straight-line basis through the Retention Period End Date. The remaining $

0.5

million of the incremental non-cash stock-based compensation expense is associated with unvested Repriced Options and will be recognized as follows: (a) if the Retention Period is greater than the remaining original vesting period of the Repriced Option, the incremental cost will be amortized on a straight-line basis through the Retention Period End Date or (b) if the Retention Period is less than the remaining original vesting term of the Repriced Option, the incremental cost will be amortized on a straight-line basis over the remaining original vesting period.

During the year ended December 31, 2023, the Company recognized incremental stock-based compensation expense totaling $

0.3

million associated with the repricing which is included in general and administrative and research and development expense on the consolidated statement of operations and comprehensive loss.

2018 Equity Incentive Plan

In October 2018, the Company adopted the 2018 Equity Incentive Plan (the 2018 Plan) which replaced the Company's legacy 2017 Equity Incentive Plan (the 2017 Plan). The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other forms of stock awards. As of December 31, 2023, the 2018 Plan had a maximum of

576,464

total shares available for issuance. The number of shares of common stock reserved for issuance under the 2018

Plan will automatically increase on January 1 of each calendar year through January 1, 2028, in an amount equal to 5.0% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board.

Options granted under the 2018 Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option shall be determined by the Board based on the estimated fair value of the Company's stock on the date of the option grant. The exercise price shall not be less than

100
% of the fair market value of the Company's common stock at the time the option is granted. Most option grants generally vest

25
% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years .

Stock Options

The following summarizes stock option activity for the year ended December 31, 2023:

	Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands) (a)
Balances as of December 31, 2022	5,102,501	$ 4.11		
Granted	2,446,300	$ 0.99		
Exercised	-	$ -		
Forfeitures and cancellations	(517,726)	$ 2.17		
Balances as of December 31, 2023 **(b)**	7,031,075	$ 0.90	7.57	$ 27
Options exercisable as of December 31, 2023 **(b)**	3,737,311	$ 1.01	6.63	$ 5

(a) Aggregate intrinsic value in this table was calculated as the positive difference, if any, between the closing price per share of the Company's common stock on December 31, 2023, of $

0.72
and the price of the underlying options.

(b) The weighted-average exercise price per share of the options outstanding and exercisable as of December 31, 2023, includes the impact of the repricing of

6,628,589
options on August 14, 2023, at $

0.785
per share.

There were

no

stock options exercised for the years ended December 31, 2023 and 2022.

The fair value of stock options that vested in the years ended December 31, 2023 and 2022 was $

4.1
million and $

4.5
million, respectively. The weighted-average grant-date fair value of options granted was $

0.69
and $

2.49
for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, unrecognized compensation expense related to unvested stock options was $

5.3
million and is expected to be recognized over a weighted-average period of 2.52 years.

2018 Employee Stock Purchase Plan

In October 2018, the Company adopted the 2018 Equity Stock Purchase Plan (ESPP) whereby eligible employees may elect to withhold up to

15
% of their earnings to purchase shares of the Company's common stock at a price per share equal to the lower of (i)

85
% of the fair market value of a share of the Company's common stock on the first date of an offering or (ii)

85
% of the fair market value of a share of the Company's common stock on the date of the purchase right (purchase right). Initially,

343,275
shares of the Company's common stock were approved for issuance under the ESPP pursuant to purchase rights granted to the Company's employees or to employees of any of the Company's designated affiliates. The number of shares of the Company's common stock reserved for issuance will automatically increase on January 1 of each calendar year through January 1, 2028, by the lesser of (1) 1.0% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (2)

343,275
shares; provided that before the date of any such increase, the Board may determine that such increase will be less than the amount set forth in clauses (1) and (2) .

As of December 31, 2023, the Company had issued

597,272
shares of common stock under the ESPP,

289,855
of which were issued during the year ended December 31, 2023. The Company had

979,383
shares available for future issuance under the ESPP as of December 31, 2023.

Stock-based Compensation Expense

Total non-cash stock-based compensation expense for all stock awards and purchase rights, net of forfeitures recognized as they occur, that was recognized in the consolidated statement of operations is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 1,549	$ 1,799
General and administrative	2,448	3,042
Total	$ 3,997	$ 4,841

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants were as follows:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.93 %	1.93 %
Expected volatility	78.22 %	81.60 %
Expected term (in years)	6.04	5.84
Expected dividend yield	0 %	0 %

Risk-free interest rate. The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.

Expected volatility. Due to the Company's limited operating history and lack of company-specific historical or implied volatility as a private company, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

Expected term. The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Expected dividend yield. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does

no
t intend to pay dividends.

Forfeitures. The Company reduces stock-based compensation expense for actual forfeitures during the period.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following as of December 31, 2023 and 2022:

	December 31,	
	2023	2022
Stock options issued and outstanding	7,031,075	5,102,501

Warrants for common stock	1,366,141	1,366,141
Awards available under the 2018 Equity Incentive Plan	576,464	784,331
Employee stock purchase plan	979,383	925,963
Total	9,953,063	8,178,936

12. Commitments and Contingencies

Leases and Other Commitments

As of December 31, 2023, the Company leased certain office and laboratory space in La Jolla, California under non-cancelable operating leases, including a lease for laboratory space that expires in February 2025 and leases for office space that expire in February 2027. The Company previously leased office space in South San Francisco, California under a lease that expired in February 2023.

The Company enters into service agreements with indemnification clauses in the ordinary course of business. Pursuant to such clauses, the Company indemnifies, defends, holds harmless, and agrees to reimburse the indemnified party for losses

suffered or incurred by third party claims arising out of the indemnified party's performance of service. The Company has not incurred costs to defend lawsuits pursuant to these indemnification clauses.

Litigation

As of December 31, 2023, there was

no
litigation against the Company.

13. Income Taxes

The components of loss before income tax provision (benefit) for the years ended December 31, 2023 and 2022 consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
U.S.	(7,659)	(60,403)
Foreign	(5,096)	(2,025)
	$ (12,755)	$ (62,428)

During the year ended December 31, 2023, the Company recorded a current federal tax expense of $

564,000
and a current state expense of $

16,000
. The Company has

no

t recorded a current or deferred tax expense or benefit for the year ended December 31, 2022.

The following is a reconciliation of the expected statutory federal income tax provision to our actual income tax provision for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Income taxes at statutory rates	$ (2,679)	$ (13,110)
State income tax, net of federal benefit	1,802	(1,681)
Stock-based compensation	(728)	533
Officers compensation	1,379	-
Permanent items	55	95
Research and orphan drug credits	(619)	(1,493)

Foreign rate differential	448	243
Acquired in-process research and development	-	4,840
Change in valuation allowance	922	10,573
	580	-

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2023 and 2022 are as follows (in thousands):

	December 31, 2023	2022
Deferred tax assets:		
Net operating loss carryforward	$ 19,562	$ 28,222
Credits	8,314	9,289
Capitalized research expenditures	4,235	7,086
Deferred revenue	12,748	-
Equity compensation	1,801	1,829
Other	781	1,196
Total deferred tax assets	47,441	47,622
Valuation allowance	(47,213)	(46,317)
Total deferred tax assets, net of allowance	$ 228	$ 1,305
Deferred tax liabilities:		
Operating lease right-of-use asset	(167)	(284)
Deferred revenue	-	(945)
Other	(61)	(76)

Total deferred tax liabilities	($ 228)	($ 1,305)

The Company has established a valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of $

47.2

million as of December 31, 2023, as it does not believe it is more likely than not that certain deferred tax assets will be realized primarily due to the generation of pre-tax book losses in the current year, the lack of feasible tax-planning strategies, the limited existing taxable temporary differences, and the subjective nature of forecasting future taxable income into the future. The Company increased its valuation allowance by approximately $

0.9

million during the year ended December 31, 2023.

At December 31, 2023, the Company had federal and California tax loss carryforwards of approximately $

76.9

million and $

76.5

million, respectively. The federal net operating loss carryover includes $

76.9

million of net operating losses generated subsequent to 2017. Federal net operating losses generated after December 31, 2017, carryover indefinitely but the deductibility of such federal net operating losses is limited to

80

% of taxable income. The federal net operating losses of $

76.9

million were generated after December 31, 2017 and may be carried over indefinitely, but the deductibility of such losses is limited to

80

% of federal taxable income. The state net operating loss carryforwards, begin to expire in 2037 unless previously utilized. The Company has $

4.8

million of Australian net operating loss carryforwards as of December 31, 2023, that are carried forward indefinitely.

At December 31, 2023, the Company had federal and state tax credit carryforwards of approximately $

6.1

million and $

2.8

million, respectively, after reduction for uncertain tax positions. The Company has not performed a formal research and development credit study with respect to these credits. The federal credits will begin to expire in 2040 , if unused, and the state credits carryforward indefinitely.

Pursuant to the Internal Revenue Code of 1986, as amended (IRC), specifically Sections 382 and 383, the Company's ability to use tax attribute carryforwards to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than

50

% within a three-year testing period. The Company completed an ownership change analysis through June 30, 2023, pursuant to IRC Section 382 and determined that the Company's ability to offset taxable income in 2023 is not expected to be impacted by ownership changes occurring prior to that date. If ownership changes within the meaning of IRC Section 382 occur in the future, the amount of remaining tax attribute carryforwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated, including those acquired through Bioniz. Further, the Company's deferred tax assets associated with such tax attributes could be significantly reduced or eliminated upon realization of an ownership change within the meaning of IRC Section 382. If eliminated, the related asset would be removed from the deferred tax asset schedule, with a corresponding reduction in the valuation allowance. Additionally, limitations on the utilization of the Company's tax attribute carryforwards can increase the amount of taxable income and current income tax expense recognized. Due to the existence of the valuation allowance, ownership change limitations that are not significant may not impact the Company's effective tax rate.

The following table summarizes the reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Unrecognized tax benefits – beginning	$ 5,879	$ 5,487
Gross increases – tax positions in prior period	83	-
Gross decreases – tax positions in prior period	-	-
Gross increase – current-period tax positions	113	392
Gross decrease – current-period tax positions	-	-
Settlements	-	-

Lapse of statute of limitations	-	-
Unrecognized tax benefits – ending	$ 6,075	$ 5,879

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal corresponding adjustment in the deferred tax asset valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's consolidated balance sheet as of December 31, 2023, and

has not recognized interest and/or penalties in the consolidated statement of operations for the year ended December 31, 2023.

All tax years for both federal and state purposes remain open and subject to examination by tax jurisdictions. The Company is subject to taxation in the United States, various U.S. state jurisdictions and Australia.

The 2017 tax reform act amended the IRC, effective for amounts paid or incurred in tax years beginning after December 31, 2021, to eliminate the immediate expensing of research and experimental (R&E) expenditures and require taxpayers to charge their R&E expenditures and software development costs (collectively, R&E expenditures) to a capital account. Capitalized costs are required to be amortized over five years (15 years for expenditures attributable to foreign research).

Income tax expense was $

0.6

million for the year ended December 31, 2023. The Company's 2023 income tax expense was primarily attributable to domestic cash tax expense resulting from differences between book and tax treatment of certain items. The Company does not record a deferred tax provision as there is a full valuation allowance offsetting the Company's net deferred tax assets. There was

no

income tax expense for the year ended December 31, 2022.

14. Retirement Plan

The Company sponsors an employee savings plan that qualifies as a deferred salary arrangement under Section 401(k) of the IRC. Participating employees may defer up to the Internal Revenue Service annual contribution limit. The Company did

no

t make any contributions for the years ended December 31, 2023 or 2022.

15. Subsequent Events

On March 6, 2024, upon the recommendation of the Compensation Committee of the Board, the Board adopted and approved the Company's 2024 Inducement Plan (the Inducement Plan) to reserve

1,500,000

shares of the Company's common stock to be used exclusively for grants of equity awards to individuals that were not previously employees or directors of the Company (or who are returning to employment following a bona fide period of non-employment), as an inducement material to the individual's entry into employment with the Company, pursuant to Nasdaq Listing Rule 5635(c)(4). The Inducement Plan was adopted and approved without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). In addition, the Board adopted and approved forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise for use with the Inducement Plan. The terms and conditions of the Inducement Plan are substantially similar to the Company's stockholder-approved 2018 Plan.

Exhibit 21.1

SUBSIDIARIES OF EQUILLIUM, INC.

Name of Subsidiary	Jurisdiction of Incorporation
Equillium AUS Pty Ltd.	Australia
Bioniz Therapeutics, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Equillium, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-269154, 333-263790, 333-254656, 333-237407, 333-230536 and 333-227859) on Form S-8, and (No. 333-269153) on Form S-3 of our report dated March 25, 2024, with respect to the consolidated financial statements of Equillium, Inc. and subsidiaries.

/s/ KPMG LLP

San Diego, California
March 25, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Bruce D. Steel, certify that:

1. I have reviewed this annual report on Form 10-K of Equillium, Inc., a Delaware corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2024

/s/ Bruce D. Steel
Bruce D. Steel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Jason A. Keyes, certify that:

1. I have reviewed this annual report on Form 10-K of Equillium, Inc., a Delaware corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2024

/s/ Jason A. Keyes
Jason A. Keyes
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, each of the undersigned hereby certifies in his capacity as an officer of Equillium, Inc. (the "Company"), that, to the best of his knowledge:

(1)the Company's Annual Report on Form 10-K for the annual period ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2)the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Bruce D. Steel
Bruce D. Steel
Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2024

/s/ Jason A. Keyes
Jason A. Keyes
Chief Financial Officer
(Principal Financial Officer)

Date: March 25, 2024

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Equillium, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), in such filing.

Exhibit 97.1

EQUILLIUM, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of **EQUILLIUM, INC.**, a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4.RECOUPMENT

(a)Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed. In no event shall the Company be required to award a Covered Officer an additional payment if the restated or accurate financial results would have resulted in a higher Incentive Compensation payment.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation. Notwithstanding the foregoing, the Company makes no guarantee as to the compliance of the recoupment with Code Section 409A and shall have no liability with respect thereto.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Revocable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to Sox 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *