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, 2021

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) 412-5302

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 Global 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. ☐

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, 2021 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $95.3 million based on the closing price of the registrant's common stock on June 30, 2021 of $5.89 per share, as reported by the Nasdaq Global Market.

As of March 18, 2022, there were 34,275,898 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 2022 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, 2021. 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: 185 Auditor Name: KPMG LLP Auditor Location: San Diego, California, United States

Table of Contents

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;
- our estimated timeline for announcing data from our clinical trials, for interacting with regulatory authorities, and for initiating clinical trials in 2022;
- our ability to obtain funding for our operations, including funding necessary to commence and complete the clinical trials of our product candidates;
- the success, cost, and timing of our product development activities, including our ongoing and planned clinical trials;
- 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 expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act, as amended, or JOBS Act;
- 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 complete the development and any commercialization of itolizumab (EQ001) and our other 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 success of our lead product candidate, itolizumab (EQ001), which is in clinical development, and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate in any of the indications for which we plan to develop it;
- Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical trials 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 trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- 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 clinical trials conducted by Biocon or third parties in other jurisdictions may affect our ability to obtain regulatory approval or commercialize itolizumab;
- We depend on intellectual property related to itolizumab licensed from Biocon, and termination of our license could result in the loss of significant rights, which would harm 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 biologics is complex and Biocon, our exclusive manufacturer of itolizumab, may encounter difficulties in production, distribution and delivery of itolizumab. If Biocon encounters such difficulties, our ability to provide supply of itolizumab (EQ001) for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of itolizumab (EQ001), if approved, could be delayed or stopped;
- We rely, and intend to continue to rely, on contract research organizations (CROs) to conduct our clinical trials and perform some of our research and preclinical studies. If these 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;
- 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, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success; and
- The novel coronavirus global pandemic has adversely impacted our business, including our clinical trials, and could further impact other aspects of our business including our supply chain, personnel, and our business development activities, the magnitude and extent of which are uncertain.

PART I

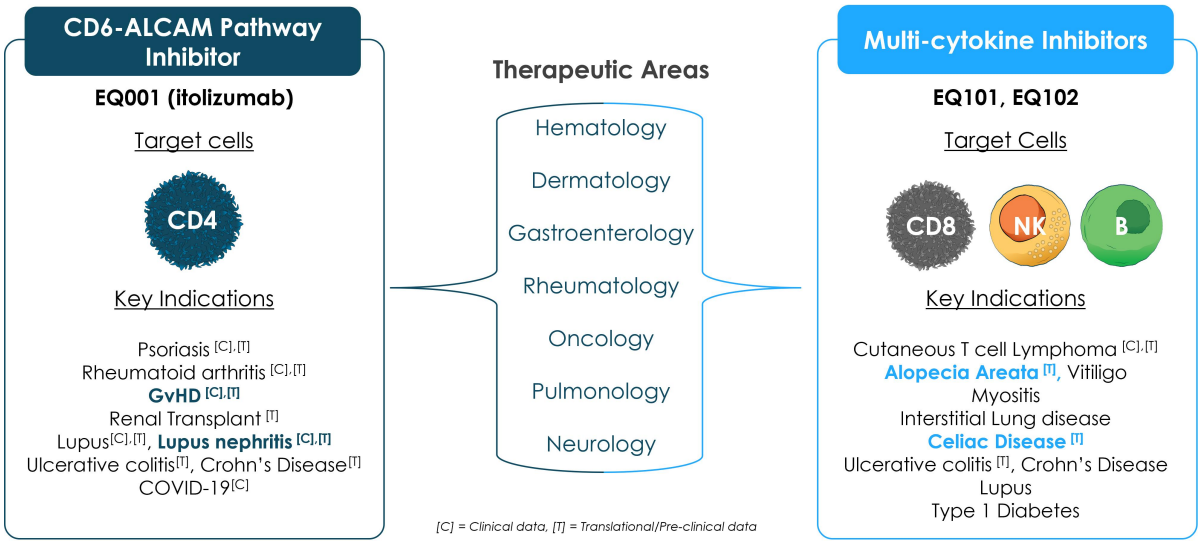
Item 1. Business.

Overview

We are a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop novel therapeutics to treat severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need. Our initial product candidate, itolizumab (EQ001), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6. CD6 plays a central role in the modulation of effector T cell, or T_{eff} cell, activity and trafficking, which drives a number of immuno-inflammatory diseases across multiple therapeutic areas. Therefore, we believe itolizumab (EQ001) may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.

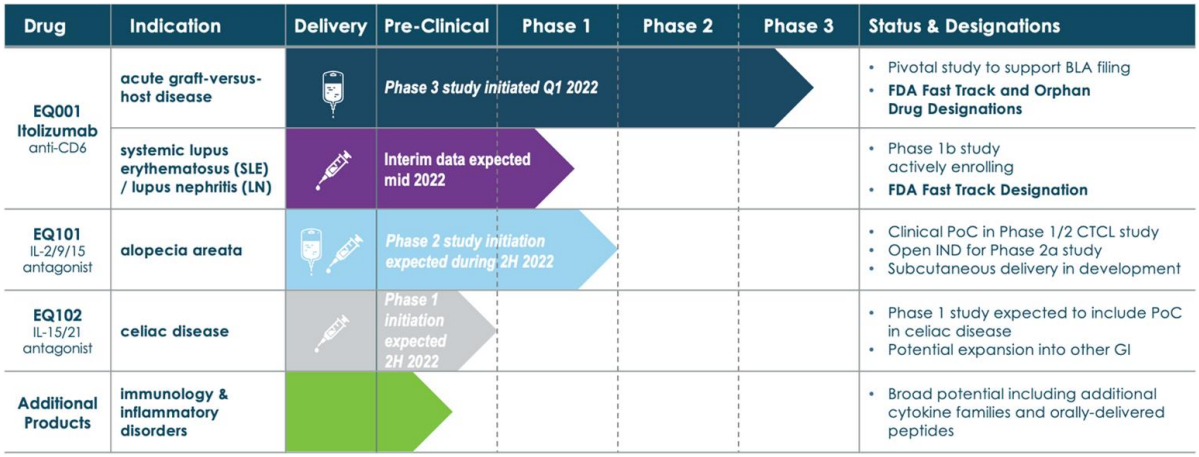
In February 2022, we expanded our pipeline of novel immunomodulatory drug candidates, adding two first-in-class clinical stage assets, EQ101 and EQ102, and a proprietary product discovery platform, through the acquisition of Bioniz Therapeutics, Inc., or Bioniz, a privately held, clinical stage biotechnology company. Lead assets acquired are specific multi-cytokine inhibitors of key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immune-inflammatory indications.

This novel and differentiated pipeline of first-in-class immunology assets has the potential to address unmet medical needs in numerous areas, including transplant science, hematology, dermatology, gastroenterology, rheumatology, oncology and pulmonology.



Our pipeline is focused on developing itolizumab (EQ001), EQ101 and EQ102 as potential best-in-class, disease modifying treatments for multiple severe immuno-inflammatory disorders. We currently have active clinical development programs for itolizumab (EQ001) for the treatment of acute graft-versus-host disease, or aGVHD and lupus/lupus nephritis. In the fourth quarter of 2021, we completed a Phase 1b study of itolizumab (EQ001) in patients with uncontrolled asthma and met our primary objective of safety and tolerability. However, as a result of the ongoing pandemic and associated challenges conducting asthma trials, we decided to prioritize our clinical development efforts of itolizumab (EQ001) in our ongoing programs in aGVHD and lupus/lupus nephritis and will be reassessing our potential future development strategy in asthma. We are in the process of planning for the clinical development of EQ101 and EQ102 and currently expect to initiate a Phase 2 study of EQ101 in alopecia areata and a Phase 1 study of EQ102 in celiac disease, both in the second half of 2022.

The following chart summarizes the status of our current clinical development programs. Details for each program are outlined in ‘Our Initial Clinical Indications’ section below.



We have ongoing translational biology programs to assess the therapeutic utility of itolizumab (EQ001) in additional indications where CD6 and its ligand, activated leukocyte cell adhesion molecule (ALCAM), play an important role in the pathogenesis of T cell mediated diseases. In addition, through the acquisition of Bioniz, we now also 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. 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.

Acquisition

On February 14, 2022, we acquired Bioniz Therapeutics, Inc., or Bioniz, pursuant to the terms of an Agreement and Plan of Merger under which our wholly-owned subsidiary merged with and into Bioniz, with Bioniz surviving as our wholly-owned subsidiary, or the Merger. As consideration for the Merger, we agreed to (i) issue up to an aggregate of 5,699,492 shares of our Common Stock, and (ii) 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 the first U.S. approval, and up to an aggregate of $250 million based on the achievement of certain commercialization events for product candidate EQ101 (formerly identified as BNZ-1). Through our acquisition of Bioniz, we expanded our immunology pipeline with a diversified portfolio of first-in-class immune-inflammatory product candidates across a range of development stages. See Note 14 of the Notes to Financial Statements, including in Item 15 of this Annual Report on Form 10-K, for further details of this acquisition.

Partnerships

Collaboration and License Agreement with Biocon

Equillium 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). The agreement, or Biocon License, was amended in September 2018, April 2019 and December 2019, pursuant to which Biocon granted Equillium 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, or collectively, a Biocon Product, in the United States, Canada, Australia and New Zealand, or the Equillium Territory. In August 2019, we entered into a letter agreement with Biocon that grants us exclusive rights to negotiate licensing rights with third parties to develop and commercialize itolizumab (EQ001) in select major markets outside of North America. This letter agreement allows us to represent itolizumab (EQ001) more broadly commercially and participate in value that may be created with strategic partners across geographies. Our collaboration with Biocon includes an exclusive supply agreement for clinical and commercial drug product of itolizumab (EQ001). 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 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 trials, subject to adjustments in certain circumstances. Under the Biocon License, 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.

The Biocon License will continue until the expiration of all royalty obligations, unless terminated earlier. We are obligated to pay royalties on a product-by-product and country-by-country basis from the first commercial sale of a Biocon Product in a country until the latest of ten years from the first commercial sale of such Biocon Product in such country, the expiration of regulatory exclusivity for such Biocon Product in such country, and the expiration of the last-to-expire Biocon patent covering such Biocon Product in such country. We may terminate the Biocon License unilaterally, with or without reason, upon 120 days' prior written notice and either party may terminate the Biocon License in the event of the other party's material breach of the Biocon License that remains uncured for 90 days after receipt of notice from the non-breaching party. Upon termination by us unilaterally or by Biocon for our material breach, Biocon will retain its license to use our intellectual property related to itolizumab and Biocon Products in certain countries outside the Equillium Territory, and we also will grant Biocon a non-exclusive license, and a right of first negotiation to an exclusive license, to use our intellectual property related to itolizumab and Biocon Products in the Equillium Territory. Further, we are subject to certain diligence obligations related to development, commercialization and funding activities and if we fail to comply with these obligations Biocon may, in certain circumstances, terminate the Biocon License and, in certain other circumstances, such failure may result in the permitted fields of use for licensed Biocon Products being limited to orphan indications and the treatment of asthmatic conditions.

Clinical Supply Agreement with Biocon

In May 2017, in connection with the Biocon License, we entered into a clinical supply agreement, or the Biocon Supply Agreement, with Biocon, pursuant to which Biocon agreed to be our exclusive supplier of itolizumab clinical drug product. Under the terms of the Biocon Supply Agreement, we receive clinical drug product at no cost for up to three concurrent orphan drug clinical indications until our first U.S. regulatory approval and all other clinical drug product at Biocon's cost. The Biocon Supply Agreement will remain in effect until the expiration or termination of the Biocon License.

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 itolizumab (EQ001) for the treatment of GVHD.** We are currently conducting the EQUATE study, a Phase 1b clinical study of itolizumab (EQ001) as a first-line therapy concomitant with steroids for the treatment of aGVHD. In this study we are assessing safety, pharmacokinetics, or PK, pharmacodynamics, or PD, and a number of clinical outcomes including complete response rate, overall response rate, survival and steroid taper. In June 2021, we announced positive topline results from 20 patients in the study, and in December 2021 at the annual meeting of the American Society of Hematology we reported additional data from a total of 25 patients treated with itolizumab (EQ001) at doses of 0.4, 0.8 or 1.6 mg/kg. In patients treated with itolizumab (EQ001) within 3 days of first steroid administration (n=18), Day 29 complete response rates were 61% (11 of 18). Among the patients that were evaluated at Day 169, outcomes were notable for durability of responses with 50% (11 of 22) of patients achieving a complete response and overall survival rate of 64% (14 of 22), with a total of 12 of 14 (86%) responders alive at Day 169 compared to 2 of 8 (25%) non-responders. Responders also experienced a clinically meaningful mean reduction in steroid administration during the evaluation period. Itolizumab (EQ001) treatment was well tolerated across all doses, with reported adverse events consistent with a hospitalized severe aGVHD population, with 2 of 25 subjects (8%) reporting treatment-related serious adverse events, or SAEs. Itolizumab (EQ001) treatment resulted in a dose-dependent reduction of CD6 expression on CD4+ T cells and an increase in the regulatory to effector T cell ratio in patients, consistent with the drug's mechanism of action. In March 2022, we initiated the EQUATOR study, a pivotal Phase 3 clinical study of itolizumab (EQ001) in patients with aGVHD. The randomized, double-blind 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 are currently conducting the EQUALISE study, a Phase 1b proof-of-concept clinical study of itolizumab (EQ001) in patients with SLE and in

patients with lupus nephritis. The completed Type A portion of the study was a multiple ascending-dose trial involving 35 SLE patients to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of subcutaneous (SC) doses of itolizumab (EQ001) every two weeks (Q2W). The ongoing Type B portion of the study will evaluate up to 20 newly diagnosed or refractory lupus nephritis (LN) patients who will be treated with itolizumab (EQ001) dosed at 1.6 mg/kg SC Q2W for up to 24 weeks. In March 2021, we reported favorable topline data from the Type A group of the EQUALISE study in patients with SLE. The data showed itolizumab (EQ001) was safe and 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. In August 2021, we announced additional data from the Type A portion of the study in a subset of SLE patients. The exploratory data set demonstrated that patients without a diagnosis of LN but with elevated urine protein/creatine ratio (UPCR) >200 mg/g (N=6, baseline geometric mean 378 mg/g) experienced a mean decrease from baseline in UPCR of 33% and 42% at Days 29 and 57 respectively, following SC doses of itolizumab (EQ001) on Days 1 and 15. Notably, one subject who had baseline UPCR of 1,505 mg/g declined to 974 mg/g at Day 29 and 857 mg/g by Day 57. Additionally, patients with elevated albumin/creatinine ratio (ACR) >30 mg/g (N=4, baseline geometric mean 97 mg/g) experienced a mean decrease from baseline in ACR of 22% and 53% at Days 29 and 57, respectively. We plan on reporting interim data from the Type B LN portion of the study in mid-2022.

- **Expand clinical development of itolizumab (EQ001) into additional indications based on our translational biology program.** We will continue to conduct preclinical and translational studies and assimilate learnings from itolizumab (EQ001) in clinical trials to help inform the selection of additional indications for future development.
- **Opportunistically expand our pipeline of product candidates.** We will leverage the collective talent within our organization to opportunistically 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 itolizumab (EQ001). We successfully executed on this component of our strategy through the acquisition of Bioniz in February 2022.
- **Build a commercial infrastructure.** If approved, we intend to commercialize itolizumab (EQ001) ourselves in indications that can be efficiently targeted using a specialty sales force, such as aGVHD and lupus nephritis. For other indications we intend to commercialize itolizumab (EQ001) either independently or through collaborations with other parties.

Understanding the Basis of Our Approach: 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_{eff} and regulatory T cells, or T_{reg} cells, see **Figure 1**.

Figure 1: 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 novel, tightly-regulated, 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.

CD6 is predominantly expressed on T helper cells, or T_h cells, and regulates T cell responses. Once activated, naïve T_h cells become T_{eff} cells and carry out specialized immune functions depending on their specific phenotype such as T_h1, T_h2 and T_h17 cells. The expression levels of CD6 are increased on T_{eff} cells and are associated with autoreactivity in cells, leading to autoimmunity. Conversely, the lower or no expression of CD6 on T_{reg} cells suggests that CD6 is not required for their regulatory function. See **Figure 2.**

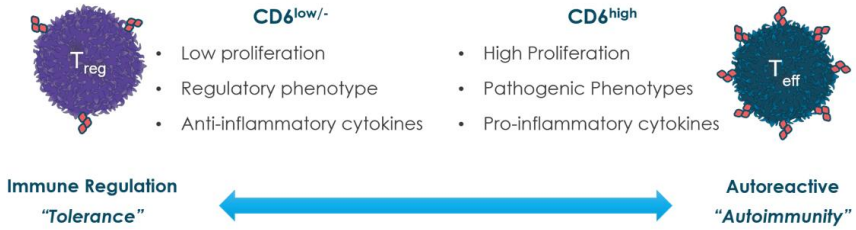


Figure 2: CD6 expression is associated with T cell function. $CD6^{high}$ T cells have increased pathogenic potential with increased proliferative capacity, secretion of proinflammatory cytokines and are associated with allo- and autoreactivity, i.e., autoimmunity. $CD6^{low/-}$ T cells have decreased pathogenic potential with decreased proliferative capacity, increased secretion of anti-inflammatory cytokines and are associated with immune regulation, i.e., tolerance.

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 3**.

Studies have shown that co-stimulation of CD6 by ALCAM enhances T cell activation and resulted in a five-fold increase in IL-2 receptor mediated T_{eff} cell proliferation. Moreover, CD6 co-stimulation promotes a preferentially pro-inflammatory response and increased secretion of T_{eff} cytokines IFN-γ, TNF-α and IL-6. Additionally, CD6 co-stimulation leads to increased expression and activation of validated targets for the treatment of immuno-inflammatory disease, including signal transducer and activator of transcription 3, or STAT3, and retinoid acid-related orphan receptor, or RORγt, the master transcriptional regulator of T_h17 cells. This results in increased expression of IL-23R and high levels of IL-17, both markers of pathogenic T_h17 cell activity and resistance to steroid treatment, which is a first-line therapy in many immuno-inflammatory diseases. T_h17 cells play an especially important role in autoimmunity: T_h17 and T_{reg} cells are reciprocally regulated and thus an increase in T_h17 cells and associated cytokines leads to suppression of T_{reg} cell activity and loss of tolerance. Studies have shown that co-stimulation through CD6 is superior to CD28 co-stimulation in driving T_h17 cell development and thus represents an attractive target for the treatment of immuno-inflammatory diseases, especially those resistant or refractory to steroid treatment.

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. Studies have shown that, in the presence of the pro-inflammatory cytokine IFN-γ, the expression of ALCAM is increased on a number of cell types, suggesting an important dual role for the CD6-ALCAM pathway in autoimmune and inflammatory responses.

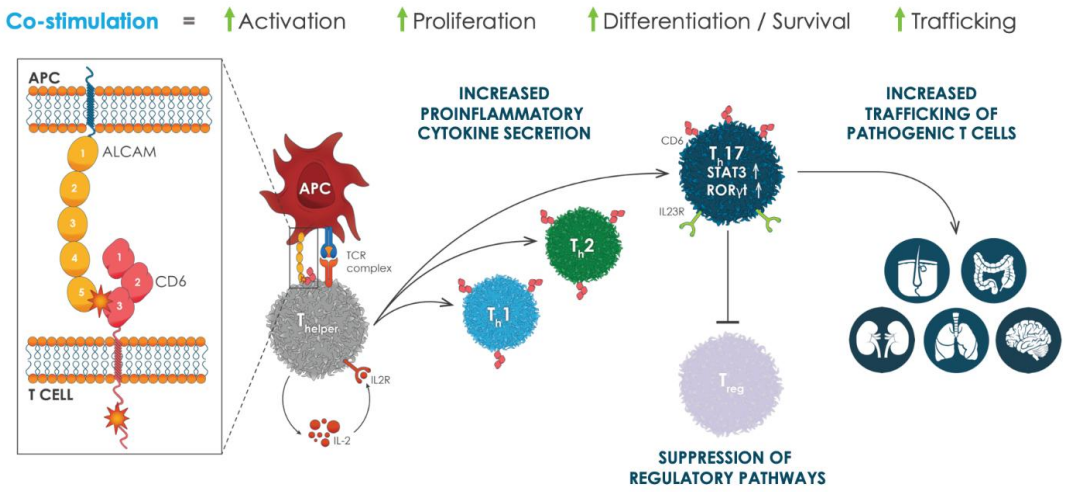


Figure 3: CD6 co-stimulation drives pathogenic T cell development and activity. Co-stimulation occurs through the binding of ALCAM to domain-3 of CD6, leading to synergistic activation resulting in a five-fold increase in IL-2 receptor mediated T_{eff} cell proliferation. Co-stimulation through CD6 promotes 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 T_h1, T_h2 and T_h17 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, inhibiting the binding of ALCAM to CD6, either by anti-CD6 monoclonal antibodies or by deletion of the gene expressing CD6, 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 4**.

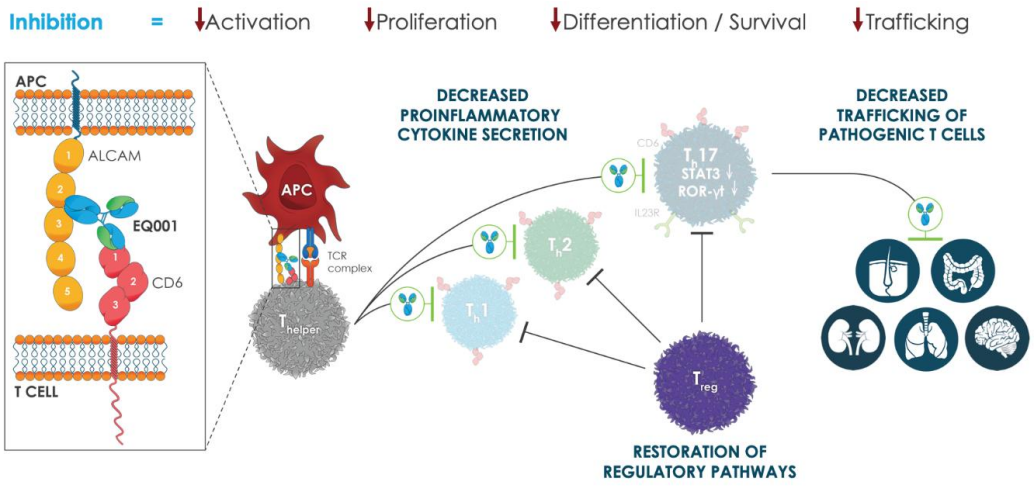


Figure 4: Blockade of CD6 by itolizumab (EQ001) inhibits T_{eff} cell activation, proliferation, differentiation and trafficking. Itolizumab (EQ001) selectively binds to domain-1 of CD6 and inhibits the interaction of ALCAM, preventing co-stimulation and thereby reducing T_{eff} cell proliferation. Blockade 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.

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

Through the acquisition of Bioniz, we acquired first-in-class assets and a proprietary platform for generating 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 JAK inhibitors. **See Figure 5**.

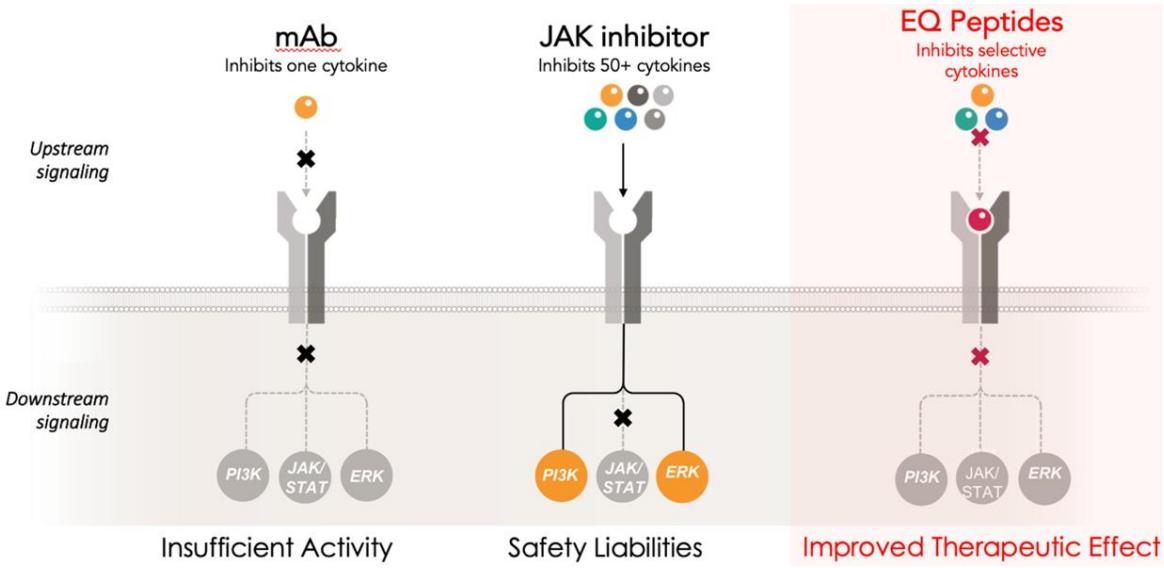
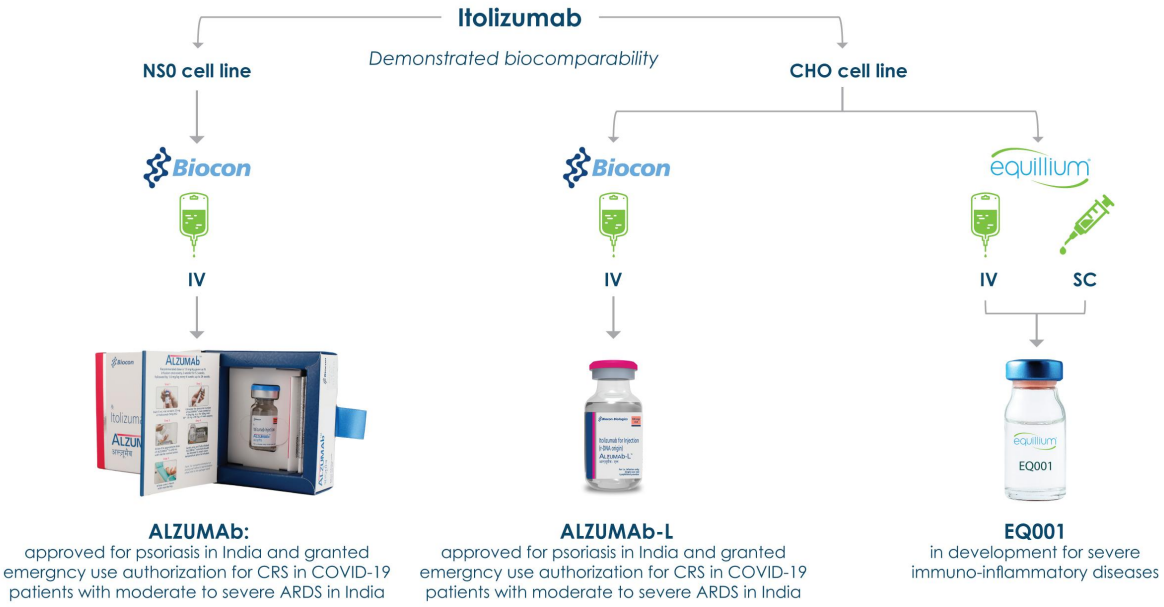


Figure 5: Rationally-designed, selective inhibition of multiple cytokines is believed to represent an optimized therapeutic modality compared to monoclonal antibodies (mAb) and JAK inhibitors.

Itolizumab (EQ001) Product Development

Itolizumab has shown activity in completed clinical trials in patients with rheumatoid arthritis, psoriasis, and acute respiratory distress syndrome (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 is produced in an NS0 cell line and is currently available only in an intravenous, or 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 via subcutaneous injection, or SC. CHO cell lines are the industry-standard antibody therapeutic production system. In September 2020, the Drugs Controller General of India (DCGI) granted approval 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 (CRS) in COVID-19 patients with moderate to severe ARDS. Moving forward, Biocon is planning on transitioning 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.



Itolizumab (EQ001) Phase 1 Clinical Trial in Healthy Subjects

Biocon conducted a Phase 1 clinical trial of itolizumab (EQ001) in 37 healthy subjects that was completed in Australia in the fourth quarter of 2017. The study was conducted in two stages, with the first stage designed to assess the safety, tolerability, PK, PD, and immunogenicity of ascending single doses of itolizumab (EQ001) SC, and the second stage designed to compare the PK of itolizumab (EQ001) IV to ALZUMAb and determine the absolute bioavailability of itolizumab (EQ001) SC.

Stage 1 was a randomized, double-blind, placebo controlled, ascending single dose evaluation of itolizumab (EQ001) SC. Thirty-two subjects completed Stage 1: 24 subjects (six per cohort) were administered itolizumab (EQ001) SC in single doses of 0.8 mg/kg, 1.6 mg/kg, 2.4 mg/kg, or 3.2 mg/kg, and eight subjects were administered placebo. Serum concentrations of itolizumab (EQ001) were measurable at Day 57, and the mean half-life ranged from 532 hours to 616 hours across dose cohorts. The PK for exposure following itolizumab (EQ001) SC administration were dose proportional, with the peak serum concentration generally achieved within 168 hours after dosing for most subjects. Saturation of CD6 receptors by itolizumab (EQ001) was seen at all dose levels. During Stage 1, a transient decrease in T cells expressing CD4, and to a lesser extent CD8, was observed, as well as a two- to three-times increase in the proportion of T_{reg} cells.

The administration of single doses of itolizumab (EQ001) SC in Stage 1 was found to be well tolerated, with a low incidence (2/24) of low titer anti-drug antibodies. There were no SAEs, dose limiting toxicities, or DLTs, or study drug discontinuations reported. No clinically meaningful changes in physical examinations or vital signs were observed, whereas transient decreases in lymphocyte counts without clinical consequences were seen in 11/24 (46%) subjects. There were five subjects who experienced grade 3 treatment emergent adverse events, or TEAEs, of lymphocyte count decreases (two subjects each in the 1.6 mg/kg and 3.2 mg/kg dose cohorts and one subject in the 2.4 mg/kg dose cohort). Mild to moderate injection site reactions were observed in 15/24 (63%) of the patients. The other most common TEAEs with itolizumab (EQ001) SC were headache in 7/24 (29%), urticaria (hives) in 4/24 (17%), and pyrexia (fever) in 3/24 (13%) of the subjects. In general, observed AEs were transient, mild to moderate in severity, were not dose dependent, and most were consistent with those observed in prior clinical experience with ALZUMAb.

Stage 2 was a comparability study of the PK of itolizumab (EQ001) IV, and ALZUMAb, and the absolute bioavailability of itolizumab (EQ001) SC. The trial featured a randomized, single-blind, parallel group design for the comparability component, and an open-label design for the absolute bioavailability component. Seven subjects enrolled in the study and received single doses of 0.4 mg/kg (one subject each itolizumab (EQ001) SC, itolizumab (EQ001) IV, ALZUMAb, and placebo) and 0.8 mg/kg (one subject each itolizumab (EQ001) SC, itolizumab (EQ001) IV, and ALZUMAb); five subjects completed the study, and one subject each that received itolizumab (EQ001) IV and ALZUMAb in the 0.8 mg/kg group discontinued dosing early due to AEs (one subject experienced persistent cough and dizziness; one subject experienced nausea). The infusion of single doses of both itolizumab (EQ001) IV and ALZUMAb was associated with the development

of transient, reversible, grade 2 to 3 decreases in lymphocyte counts in the healthy subjects. As a result, Stage 2 of the trial was terminated early following the enrollment of seven subjects, yielding limited overall safety data and insufficient PK data for evaluation. There were no SAEs reported. No other clinically meaningful abnormalities or trends were noted in clinical chemistry, hematology, and urinalysis parameters. Similar to Stage 1, a transient decrease in T cells expressing CD4, and to a lesser extent CD8, a two- to three-times increase in the proportion of T_{reg} cells, and saturation of CD6 receptors were observed across itolizumab (EQ001) and ALZUMAb cohorts.

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 in Stage 2, 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 safety and clinical activity in three clinical studies in India in patients with rheumatoid arthritis and chronic plaque psoriasis, with a total of 333 patients exposed to ALZUMAb to date in clinical trials 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 trial in healthy subjects represents a PD property of both itolizumab (EQ001) and ALZUMAb that will be monitored going forward, and the results of the Phase 1 clinical trial support the advancement of itolizumab (EQ001) SC and IV into further clinical development in patients with immuno-inflammatory disease.

Our Initial Clinical Indications

We are currently conducting clinical trials of itolizumab (EQ001) for the treatment of aGVHD and lupus/lupus nephritis. In the fourth quarter of 2021, we completed a Phase 1b study of itolizumab (EQ001) in patients with uncontrolled asthma and met our primary objective of safety and tolerability. However, as a result of the ongoing pandemic and associated challenges conducting asthma trials, we decided to prioritize our clinical development efforts of itolizumab (EQ001) in our ongoing programs in aGVHD and lupus/lupus nephritis and will be reassessing our potential future development strategy in asthma. In March 2022, we announced the initiation of our Phase 3 pivotal study, EQUATOR, in first-line aGVHD. We plan to announce interim data from the Type B lupus nephritis portion the EQUALISE study in mid-2022. In addition, we continue to evaluate other potential T cell mediated immuno-inflammatory diseases for which there is strong scientific rationale to study itolizumab (EQ001) and high unmet medical need for treatment options, which may lead us to sponsor additional clinical trials or support investigator-initiated studies or partner-sponsored studies in such indications. With respect to the product candidates acquired through the Bioniz acquisition, we are in the process of planning for their clinical development, with a current expected focus on EQ101 for alopecia areata and EQ102 for celiac disease.

Graft-Versus-Host Disease Market Overview

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 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 10,000 allo-HSCT's expected to have been performed in the United States in 2020 and the number of procedures has grown at an average annual growth rate of approximately 4% since 2007. Approximately 30-70% of 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 2020 was approximately 5,800 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 7,000 patients and the total prevalence of GVHD could be up to 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 (cGVHD).

It is well established that T_h17 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 T_h17 cells and IL-17 serum levels were significantly elevated in patients at onset compared with HSCT patients without aGVHD. As the disease progresses, T_h17 cells traffic from the peripheral blood into GVHD target tissues where they trigger damage. Furthermore, the expansion of T_h17 cells in the early phase of aGVHD plays a role in the transition to cGVHD. In GVHD patients, studies have shown a high T_h17:T_{reg} ratio suggesting a loss of tolerance. Notably the increased number of circulating T_h17 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 T_h17 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 T_h17: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 GVHD

Our Investigational New Drug application, or 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 the EQUATE study (**Figure 6),** with a primary objective to assess the safety and tolerability of IV itolizumab (EQ001) and to determine the optimal dose. Secondary objectives included the assessment of pharmacological activity of itolizumab (EQ001). All patients were administered itolizumab (EQ001) as a first-line therapy concomitant with steroid use upon first presentation of aGVHD.

The study, which reported positive topline results in June 2021, was an open-label study initially enrolling patients with Grade III-IV aGVHD that had been on systemic corticosteroids for no more than 72 hours. Following completion of the initial 3-by-3 cohort, a protocol amendment expanded enrollment to patients with Grade II aGVHD and Ann Arbor scores of 2 or 3, which allowed the inclusion of subjects with Grade II aGVHD with a higher risk of mortality and poor outcomes. That amendment also permitted the initiation of itolizumab (EQ001) from within 72 hours to within 7 days of starting systemic corticosteroids (n=7 enrolled: 3 in the 0.8 mg/kg cohort and 4 in the 1.6 mg/kg cohort). A protocol clarification letter was then issued permitting up to 15 additional subjects to be dosed with itolizumab (EQ001) at 0.8 mg/kg who met the original criteria of initial itolizumab (EQ001) dosing within 72 hours of starting systemic corticosteroids. Overall, data from the study demonstrated that itolizumab (EQ001) was safe and well tolerated in this severe aGVHD patient population and suggested an optimal dose range of 0.8 to 1.6 mg/kg IV every two weeks.

In June 2021, we completed an End-of-Phase 1 meeting with the FDA for itolizumab (EQ001) in first-line treatment of patients with aGVHD. The meeting confirmed a path to advance itolizumab (EQ001) into a Phase 3 pivotal study to support a potential Biologics License Application, or BLA, filing. The FDA provided guidance on the study design, as well as advice on chemistry, manufacturing and controls, or CMC, and nonclinical and regulatory-related topics to support Equillium's proposed pivotal clinical study and potential BLA submission of itolizumab (EQ001) for the first-line treatment of aGVHD

in combination with corticosteroids. Based on these findings and feedback from both the FDA and leading physicians in the field of hematopoietic stem cell transplantation, we initiated EQUATOR in March 2022, a Phase 3 pivotal study in first-line aGVHD.

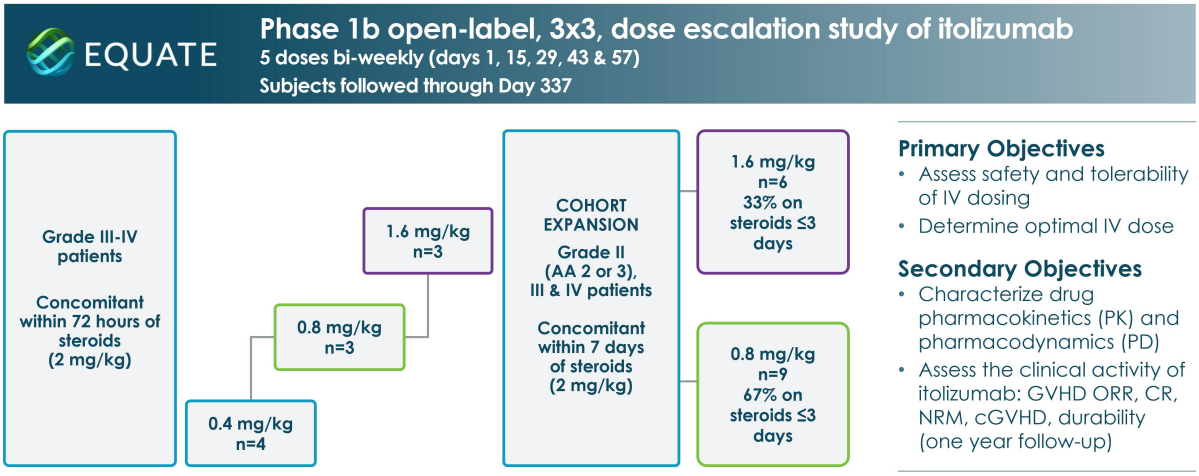


Figure 6: Overview of the EQUATE study design

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.

Lupus nephritis 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 lupus nephritis 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 lupus nephritis, called proliferative lupus nephritis or Class III or IV lupus nephritis, consists of broad-based immunosuppressive drugs, such as prednisolone, mycophenolate mofetil, or MMF, and cyclophosphamide, which come with significant toxicities. Lupus nephritis 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 lupus nephritis patients, as many as 50-75% of patients are refractory to treatment and those that respond will likely relapse within 5 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 lupus nephritis 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 lupus nephritis patients, particularly those that are refractory or relapse to standard induction therapy. Recently, two new therapies have been approved for lupus nephritis. GlaxoSmithKline's Benlysta, which was approved for lupus nephritis 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 recent approvals, there remains a significant need for new therapies that are more effective, can maintain a durable response, and carry a better safety profile. Given the high unmet medical need, we will focus our approach initially on lupus nephritis patients.

Rationale for Itolizumab (EQ001) for the Treatment of Lupus Nephritis

Itolizumab (EQ001) Selectively Targets T_{eff} Cells That Play a Central Role in the Pathogenesis of Lupus Nephritis

Despite the presence of autoantibody formation and inflammatory cytokines in SLE and lupus nephritis, 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 lupus nephritis 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 T_h1/IFN-γ, T_h2/IL-4 and T_h17/IL-17, have all been implicated in the immunopathogenesis of both SLE and lupus nephritis, highlighting the complex nature of the disease. However, T_h17 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 lupus nephritis. Elevated levels of T_h17 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 lupus nephritis.

We believe the unique mechanism of action of itolizumab (EQ001) can selectively target elements of the underlying pathogenesis of lupus nephritis 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 T_h17:T_{reg} ratio associated with lupus nephritis.

Translational Research Supporting Itolizumab (EQ001) in Lupus Nephritis

Given the central role that T_{eff} cells play in the immunopathogenesis of SLE and lupus nephritis (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 lupus nephritis 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 lupus nephritis have substantial elevations in urinary ALCAM and that ALCAM levels in the urine track with disease activity. See **Figure 7**. These data further highlight the potentially important pathogenic role of the CD6-ALCAM pathway in patients with lupus nephritis.

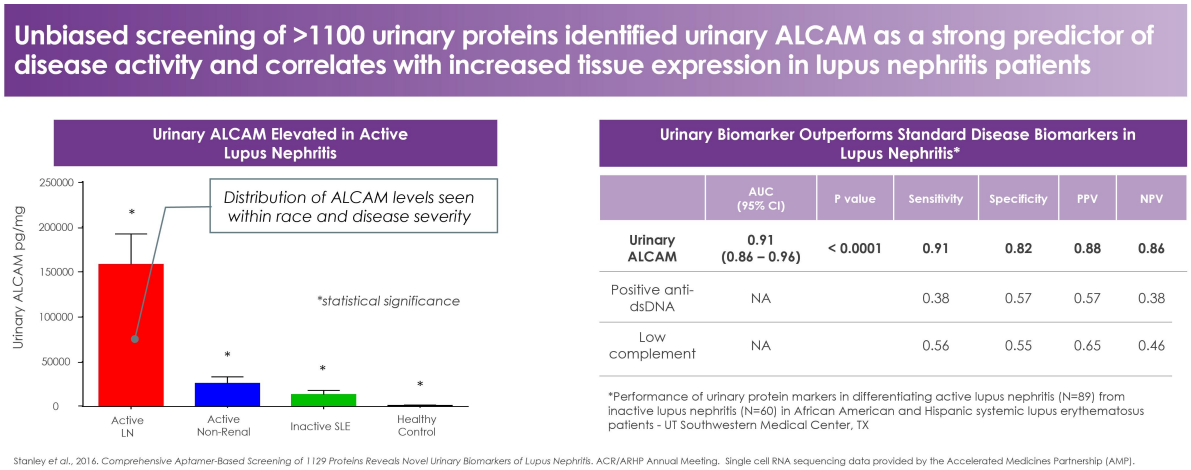


Figure 7: ALCAM is a predictive biomarker in patients with active lupus nephritis. The graph depicts levels of ALCAM in the urine of active lupus nephritis, active (non-renal) SLE, inactive SLE and healthy controls by ELISA. ALCAM was highest in active lupus nephritis patients while SLE patients were higher than healthy controls. The table compares the 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.

In addition to target validation, this research on urinary biomarkers may also have important implications in how we develop itolizumab (EQ001) in lupus nephritis. 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 lupus nephritis. 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 Lupus Nephritis

In July 2019, our IND for lupus/lupus nephritis was accepted by the FDA, and in December 2019 the FDA granted itolizumab (EQ001) Fast Track designation for the treatment of lupus nephritis. The EQUALISE study (**Figure 8)**, a Phase 1b proof-of-concept multiple ascending dose clinical trial for the treatment of lupus nephritis is comprised of two parts. The first part, Type A, has been completed and focused on evaluating the safety and tolerability of itolizumab (EQ001) in patients with SLE. The second part, Type B, is evaluating itolizumab (EQ001) in lupus nephritis patients where, in addition to safety and tolerability, potential clinical activity of itolizumab (EQ001) will be assessed based on proteinuria levels and SLEDAI-2K scores.

In September 2020 the Type A part of the study was amended to test doses up to 3.2 mg/kg in lupus nephritis patients, allow for a longer duration of treatment up to 26 weeks, and to change the design to an open-label study. 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 safe and 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.

In August of 2021, we implemented an amendment to the Type B part of the EQUALISE study in lupus nephritis patients. The amended study is evaluating up to 20 patients dosed at 1.6 mg/kg subcutaneously bi-weekly 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. We intend to announce interim data from the Type B part of the study in mid-2022.

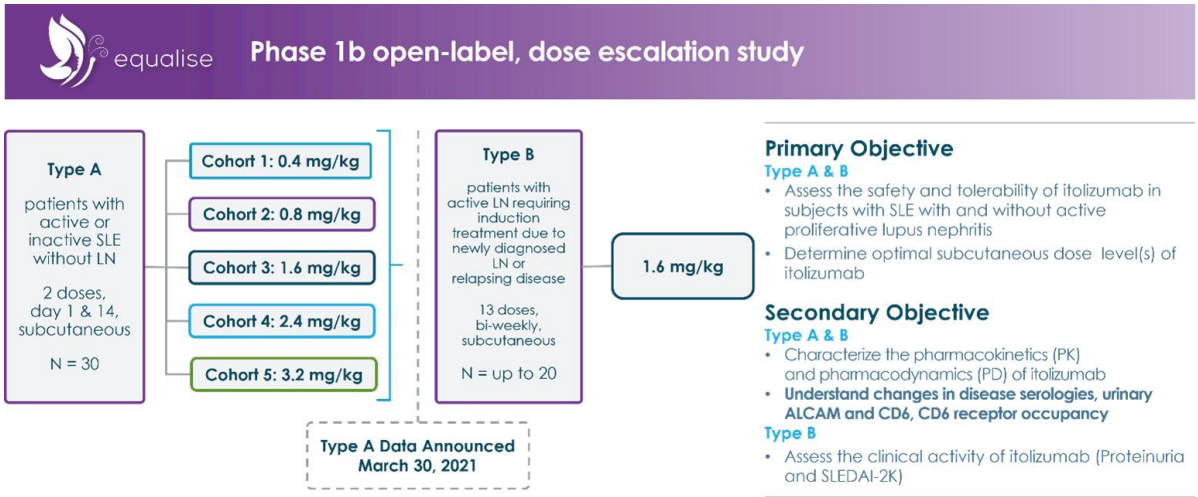


Figure 8: Overview of the EQUALISE study design

Beyond the study's primary and secondary objectives, and based on a publication in the *Journal of Clinical Investigation* in January 2022, we may also include the co-development and validation of a diagnostic biomarker related to the CD6-ALCAM pathway and other urinary biomarkers as part of the study, with focus on generating initial data to support the strategy of developing a companion diagnostic to identify lupus nephritis patients most likely to respond to itolizumab (EQ001).
Including biomarker development in early-stage clinical trials can guide us on how best to use urinary biomarkers in later stages of clinical development and provides a basis for future regulatory interactions for defining a roadmap for the co-development of a companion diagnostic. As such, we believe our approach is differentiated from other programs in development.

Bioniz Clinical Programs

On February 14, 2022, we acquired Bioniz, a privately held clinical-stage biotechnology company. Bioniz developed novel structured-domain peptides, including BNZ-1 and BNZ-2, entirely in-house from its proprietary product discovery platform.

The Bioniz lead product candidates are multi-specific inhibitors of key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immuno-inflammatory indications.

EQ101 Clinical Programs

EQ101 (formerly identified as BNZ-1) is a first-in-class, tri-specific inhibitor of IL-2, IL-9 and IL-15, three inflammatory cytokines implicated in multiple diseases. EQ101 selectively blocks those three key pathogenic cytokines while preserving non-pathogenic signaling related to IL-4, IL-7 and IL-21 (**Figure 9)**. EQ101 has demonstrated clinical proof-of-concept as a novel cytokine inhibitor through a completed Phase 1/2 study in cutaneous T cell lymphoma (CTCL), a dermato-oncology indication, achieving its primary objective of safety and tolerability and showing clinically meaningful improvements in mSWAT scores (modified severity-weighted assessment tool). In that study, the compound was shown to be well tolerated with a favorable safety profile with no drug-related SAEs, no dose-limiting toxicities, and no clinically significant laboratory abnormalities. EQ101 is Phase 2 ready in alopecia areata, a dermatological autoimmune disorder, and is Phase 2/3 ready in CTCL with open U.S. INDs for each indication and has orphan designation for CTCL in the U.S. and Europe. EQ101 is currently formulated for intravenous administration, with subcutaneous formulation development underway. We are currently planning to initially focus further development of EQ101 in patients suffering from alopecia areata, where currently no drugs are approved.

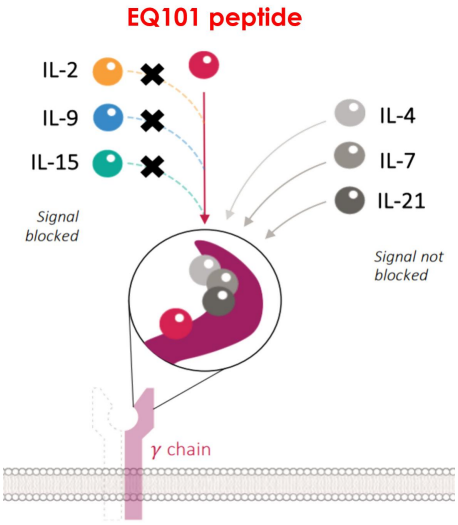


Figure 9: EQ101 inhibits IL-2, IL-9 and IL-15, but not IL-4-, IL7 and IL-21

EQ102 Clinical Programs

*EQ102 (formerly identified as BNZ-*2) is a first-in-class, selective inhibitor of IL-15 and IL-21. See **Figure 10**. EQ102 has undergone substantial translational work supporting its potential use as a treatment for various gastrointestinal diseases and is Phase 1 ready for a study planned to include a proof-of-concept evaluation in patients with 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. EQ102 is currently formulated for subcutaneous administration where it is positioned to address an unmet need in patients experiencing symptoms despite attempts to maintain a gluten-free diet.

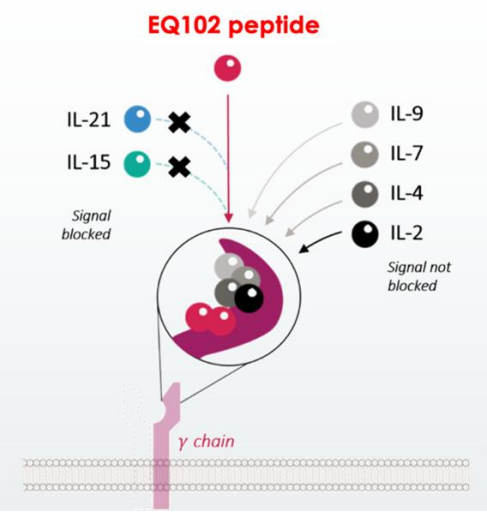


Figure 10: EQ102 inhibits IL-15 and IL-21, but not IL-2, IL-4, IL-7, and IL-9

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, 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 intended to identify additional means of obtaining patent protection that would potentially enhance commercial success, including with claims targeting newly identified compositional improvements, methods of design, methods of treating and additional therapeutic targets.

As of March 3, 2022, 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, 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" and "Business—Partnerships—Clinical Supply Agreement with Biocon.”

Specifically, as of March 3, 2022, our licensed rights from Biocon related to itolizumab included nine issued patents in the United States, five issued patents in Australia, three issued patents in Canada, five 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. Patents that may issue from our pending in-licensed patent applications are expected to expire between 2027 and 2037, 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 pending PCT application related to itolizumab dosing regimens, companion biomarkers, in vitro test lot assays, and ex vivo transplant therapies. If granted, any patents that issue from this PCT application 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 lupus nephritis 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 3, 2022, through our acquisition of Bioniz Therapeutics, Inc., we wholly own a patent portfolio directed to composite peptide antagonists. This wing of our portfolio includes six additional patent families, including those related to the IL-2, IL-9, IL-15 peptide antagonist EQ101 (formerly known as BNZ-1), the IL-15 and IL-21 peptide antagonist EQ102 (formerly known as BNZ-2), 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 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 seven issued U.S. patents, three issued Australian patents, one issued Chinese patent, 38 patents in European states, and two issued Japanese patents. Also pending are applications in the U.S., Brazil, Canada, 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 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 two 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 currently includes claims directed to composite peptides covering EQ102 and its 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 two issued U.S. patents, two issued Australian patents, 24 patents in European states, one issued Hong Kong patent, one issued Japanese patent, and one issued Korean patent. Also pending are applications in the U.S., 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 and fifth patent families include claims currently directed towards compositions and methods of treating various therapeutic targets (including, but not limited to, alopecia areata and related disorders). Collectively, these families include pending applications in the U.S., 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 2038 or 2040, absent any patent term adjustments or extensions.

The sixth patent family currently includes claims directed to EQ101 for use in methods of treating cytokine-release syndrome and related disorders. This family includes a pending PCT patent application awaiting national-phase entry. If granted, any patents in this patent family are expected to expire in 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 2 1/2 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 2 1/2 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 accorded a 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 trials, 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 trial sites and patient registration for clinical trials, 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.

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 during 2019.

In addition, we are aware of a number of companies with development programs in first-line and steroid refractory aGVHD, including CSL Behring LLC, Incyte Corporation, Humanigen, Inc., ElsaLys Biotech, Maat Pharma, AltruBio, Inc., and Xenikos B.V.

Lupus Nephritis

Standard of care induction treatment in patients with the most severe forms of lupus nephritis, called proliferative lupus nephritis or Class III or IV lupus nephritis, 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 lupus nephritis. One is GlaxoSmithKline's Benlysta, 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 lupus nephritis including Aurinia Pharmaceuticals Inc., GlaxoSmithKline plc, Bristol-Myers Squibb Company, Novartis AG, Boehringer Ingelheim GmbH, Genentech Inc., AstraZeneca plc, Kezar Life Sciences, Inc., Janssen Pharmaceuticals, Alexion Pharmaceuticals, Inc, and Omeros Corporation.

Alopecia Areata

The management of alopecia areata 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 no FDA-approved agents for treatment of alopecia areata. Clinical trials have studied JAK inhibitors and S1P modulators, among others. Companies involved in alopecia areata drug development include Concert Pharmaceuticals, Eli Lilly and Company, Pfizer Inc., and Reistone Biopharma.

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 no FDA-approved therapies for treatment of celiac disease. We are aware of a number of companies with development programs targeting the condition including 9 Meters Biopharma, Takeda Pharmaceuticals, Zedira, Provention Bio, GlaxoSmithKline, Selecta Biosciences and ImmunogenX.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of itolizumab (EQ001) and our other product candidates in the United States. We expect to manage sales, marketing, patient access and distribution through internal resources and 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.

Manufacturing

We do not own or operate manufacturing facilities for the production of itolizumab (EQ001) or any future product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently 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 trials and commercial supply of itolizumab (EQ001). If itolizumab (EQ001) is approved, we have agreed to enter into a separate exclusive supply agreement with Biocon in the future. Biocon currently 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 trials 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 trials 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 trial is commenced;
- performance of adequate and well-controlled human clinical trials 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 BLA after completion of all pivotal clinical trials that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA 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 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 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 trial with a product candidate, 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 trials 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 trial. 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 trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials 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 trials 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 trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial 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 trial 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 studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials 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 trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- 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 trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, 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.

BLA Submission, Review and Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA 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 requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA 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 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, 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, 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 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, 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 in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA 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 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 biologic 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 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.

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. 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, 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 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. 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 lupus nephritis 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 a clinical study or 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 trials 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, imposes 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 professions (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 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 must 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 trials 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 reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are 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 trials 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 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.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the FCA and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- 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;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare & Medicaid spending; and
- a licensure framework for follow on biologic products.

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. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance as part of a tax reform bill. Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. 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. Thus, the Affordable Care Act will remain in effect in its current form. 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. 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.

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 2031 unless additional Congressional action is taken. However, COVID-19 pandemic relief legislation has suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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 proposed 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. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. It is unclear whether these or similar policy initiatives will be implemented in the future. 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. Further, it is possible that additional government action is taken in response to the COVID-19 pandemic.

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 trials 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 trials 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 trials 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, 2021, we employed 45 employees, all of whom were full-time and engaged in research and development activities, operations, finance, business development and 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) 412-5302. 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.

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.

We are an "emerging growth company" as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering (i.e. December 31, 2023), (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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 preclinical research, filing three INDs, commencing clinical development of itolizumab (EQ001), conducting business development activities, 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 product sales or otherwise. 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, and we cannot estimate with precision the extent of our future losses. For the years ended December 31, 2021 and 2020, our net losses were $39.1 million and $29.8 million, respectively. As of December 31, 2021, we had an accumulated deficit of $110.0 million. We expect to incur increasing levels of operating losses for the foreseeable future as we execute our plan to continue our research and development activities into later stages of clinical development, potentially expand the indications for which we conduct clinical development of itolizumab (EQ001), potentially acquire new products and/or product candidates, seek regulatory approvals of and potentially commercialize any approved product candidates, hire additional personnel and protect our intellectual property. Furthermore, in connection with the acquisition of Bioniz, we have expanded our pipeline from one product candidate to three 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. In addition, if we obtain regulatory approval for 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 and increasing 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 trials of itolizumab (EQ001), obtaining marketing approval for itolizumab (EQ001), manufacturing, marketing and selling itolizumab (EQ001) 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 for and commercializing itolizumab (EQ001), we may never generate revenues that are significant enough to achieve profitability. In addition, as a young business, 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 complete the development and any commercialization of itolizumab (EQ001) and our other 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 research, clinical development, regulatory affairs, product quality assurance, and pharmacovigilance. In addition, if we obtain marketing approval for 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, 2021, we had $80.7 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of December 31, 2021, will enable us to fund our operations for at least the next 12 months. 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 trials of itolizumab (EQ001) may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expect. We do not have sufficient funds to complete the clinical development of itolizumab (EQ001) through regulatory approval for our current indications, and we will need to raise substantial additional capital to complete the development and commercialization of itolizumab (EQ001).

Future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of our ongoing and future clinical trials of itolizumab (EQ001), including as such activities may be adversely impacted by the COVID-19 pandemic or other pandemics;
- the number and scope of indications we decide to pursue for itolizumab (EQ001) development;
- the cost, timing and outcome of regulatory review of any BLA we may submit for itolizumab (EQ001);
- the costs and timing of manufacturing for itolizumab (EQ001), if approved;
- 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 itolizumab (EQ001);
- the costs associated with being a public company;
- 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; and
- the cost associated with commercializing itolizumab (EQ001), if approved for commercial sale.

In July 2020, we entered into an at-the-market facility with Jefferies, or the 2020 ATM Facility, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $150 million from time to time through Jefferies acting as our sales agent. As of December 31, 2021, we sold an aggregate of 788,685 shares of our common stock under the 2020 ATM Facility for gross proceeds of $10.4 million. There have been no sales of shares of our common stock under the 2020 ATM Facility since December 31, 2021 and through the date of the filing of this Annual Report on Form 10-K.

In March 2020, we entered into the Purchase Agreement, with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $15.0 million of shares of our common stock from time to time over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 65,374 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. As of December 31, 2021 and through the date of the filing of this Annual Report on Form 10-K, we have not sold any shares of our common stock to Lincoln Park under the Purchase Agreement.

In February 2021, we entered into a securities purchase agreement with institutional investors, whereby we sold 4,285,710 shares of common stock and issued warrants to purchase 1,285,713 shares of common stock for gross proceeds of $30.0 million. The warrants are exercisable immediately upon issuance at an initial exercise price of $14.00 per share and are exercisable on a cashless basis. The warrants expire on the earlier of (i) the fifth anniversary of issuance or (ii) the 15th calendar date following the date on which we close upon an equity financing that results in not less than $25 million of gross proceeds to us at a price per share of common stock equal to or greater than $25.00, at which time, all remaining warrants will automatically exercise on a cashless basis.

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. 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. In addition, the COVID-19 pandemic and conflict between Russia and Ukraine continues to rapidly evolve and have already resulted in a significant disruption of global financial markets. 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 the COVID-19 pandemic and conflict between Russia and Ukraine. If the disruption persists and deepens, we could experience an inability to access additional capital. Subject to limited exceptions, we are prohibited from incurring indebtedness without the prior written consent of the lenders pursuant to the loan agreement we entered into with Oxford Finance LLC and Silicon Valley in September 2019, as amended in December 2020, April 2021 and February 2022, or the Loan Agreement. 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.

The terms of our Loan Agreement place restrictions on our operating and financial flexibility.

In September 2019, we entered into the Loan Agreement providing for up to $20.0 million in term loans, which is secured by a first priority perfected security interest in substantially all of our current and future assets, other than our intellectual property (except rights to payment from the sale, licensing or disposition of such intellectual property). We borrowed $10.0 million upon execution of the Loan Agreement. The availability of any further credit from this Loan Agreement beyond that initial $10.0 million advancement has lapsed.

The Loan Agreement includes affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, protection of intellectual property rights, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness or liens, investments and transactions with affiliates, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions.

The Loan Agreement also includes events of default, the occurrence and continuation of which provide Oxford Finance LLC, as collateral agent, with the right to exercise remedies against us and the collateral securing the loans under the Loan Agreement, including foreclosure against our properties securing the Loan Agreement, including our cash, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. These events of default include, among other things, our failure to satisfy our payment obligations under the Loan Agreement, the breach of certain of our other covenants under the Loan Agreement, or the occurrence of a material adverse change, cross defaults to other indebtedness or material agreements, judgment defaults and defaults related to failure to maintain governmental approvals failure of which to maintain could result in a material adverse effect. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the Loan Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

Risks Related to Our Business and to the Development and Regulatory Approval of Itolizumab (EQ001)

We are highly dependent on the success of our product candidate, itolizumab (EQ001), which is in clinical development, and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate in any of the indications for which we plan to develop it.

Our future success will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize itolizumab (EQ001), in any of the indications for which we initially plan to develop it, including treatment of aGVHD, lupus nephritis and uncontrolled asthma, which may never occur. We currently generate no revenues

from sales of any biopharmaceutical products or otherwise, and we may never be able to develop or commercialize a marketable biopharmaceutical product.

Before we can market and sell itolizumab (EQ001) in the United States, we will need to manage research and development activities, commence and complete clinical trials, 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 trials and/or obtain regulatory approval and develop sufficient commercial capabilities for itolizumab (EQ001). We have not submitted a BLA to the FDA for any product candidate. Further, itolizumab (EQ001) may not receive regulatory approval even if it is successful in clinical trials. 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 itolizumab (EQ001). If itolizumab (EQ001) is approved and we fail to successfully commercialize it, 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.

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.

We have concentrated our research and development approach on targeting CD6, and our future success depends on the successful development of this therapeutic approach to the diseases we are targeting for treatment. 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. Itolizumab is approved in India for the treatment of moderate to severe plaque psoriasis, and is marketed by Biocon as ALZUMAb. Biocon was also granted restricted emergency use approval of itolizumab by the Drugs Controller General of India (DCGI) for the treatment of cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (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 may continue to be used in India on a compassionate use basis, off label, and/or in investigator-initiated studies.

We are aware of one currently active clinical study of itolizumab being conducted in Cuba in subjects with COVID-19, as well as other completed or inactive clinical studies in Cuba in Type 1 diabetes, multiple sclerosis, rheumatoid arthritis, and psoriasis. Centro de Immunologia Molecular was granted regulatory approval in Cuba for itolizumab to be used in patients with rheumatoid arthritis and psoriasis as well as emergency use approval in patients with COVID-19.

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 trials, 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 trials as a condition of marketing approval, which would increase our costs and adversely impact our business. If we receive regulatory approval for itolizumab (EQ001) and a new and serious safety issue is identified in connection with the commercial use of ALZUMAb or ALZUMAb-L or in clinical trials, 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).

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

We initiated our first clinical trial of itolizumab (EQ001) for the treatment of aGVHD in the first quarter of 2019, our second clinical trial of itolizumab (EQ001) for the treatment of uncontrolled moderate to severe asthma in the second quarter of 2019 and our third clinical trial of itolizumab (EQ001) for the treatment of lupus nephritis in the third quarter of 2019. In March 2022, we initiated a Phase 3 pivotal clinical study of itolizumab (EQ001) in patients with aGVHD. We have three active INDs with the FDA for the use of itolizumab (EQ001) in the treatment of aGVHD, lupus nephritis, and COVID-19 patients, and we have not filed an IND with the FDA for the use of itolizumab (EQ001) for the treatment of uncontrolled moderate to severe asthma. 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 trials as a company and regulatory interactions, we also cannot be certain that our ongoing and future clinical trials will be completed on time, if at all, that our planned clinical trials 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 trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials 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 trials of ALZUMAb conducted by Biocon may not be predictive of the results of our clinical trials of itolizumab (EQ001). Furthermore, our future clinical trials 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 trials, even after earlier clinical trials 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 trials have nonetheless failed to obtain marketing approval of their products. In addition, only a small percentage of biologics under development result in the submission of a BLA 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 itolizumab (EQ001). The success of itolizumab (EQ001) will further depend on factors such as:

- completion of our ongoing and future clinical trials and preclinical studies with favorable results, including activities that may be adversely impacted by the COVID-19 pandemic;
- acceptance of INDs by the FDA for our future clinical trials, as applicable;
- timely and successful enrollment in, and completion of, clinical trials with favorable results;
- demonstrating safety, efficacy and acceptable risk-benefit profile of itolizumab (EQ001) to the satisfaction of the FDA;
- receipt of marketing approvals from the FDA;
- maintaining arrangements 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 itolizumab (EQ001), if and when approved in one or more indications;
- acceptance of itolizumab (EQ001), 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 itolizumab (EQ001); and
- maintaining a continued acceptable safety profile of itolizumab (EQ001), 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 itolizumab (EQ001), which would materially harm our business.

If we fail to develop or acquire other medicine candidates or medicines, 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 in addition to itolizumab (EQ001), 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 drug 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 drug 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 medicines, our business and prospects will be limited.

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 pre-clinical 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 medicines 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 or destroy clinical trial 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 trials, 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 trial 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 trial 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 trials 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 for, 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 trials, 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.

The development and commercialization of biopharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for itolizumab (EQ001) in any of the indications for which we plan to develop it, 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 itolizumab (EQ001), currently our only product candidate, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of 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 of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls.

FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA 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 trials, failure can occur at any stage. The results of preclinical and early clinical trials of itolizumab (EQ001) or any future product candidates may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the biopharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials 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 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 trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;

- may determine that adverse events experienced by participants in our clinical trials represents an unacceptable level of risk;
- may determine that population studied in the clinical trial 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 trials, 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 FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for itolizumab (EQ001).

If we experience delays in obtaining approval or if we fail to obtain approval of itolizumab (EQ001), 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 trials could result in increased costs to us, delay or limit our ability to raise capital or generate revenue and adversely affect our commercial prospects.

Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before we can initiate clinical trials of our product candidates in any distinct indication, 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 trial protocol, as part of an IND or similar regulatory filing. To date, we have only submitted INDs for clinical trials of itolizumab (EQ001) for the treatment of aGVHD, lupus nephritis, and COVID-19. In addition, there are open INDs for EQ101 in HTLV-I-associated myelopathy/tropical spastic paraparesis, CTCL and alopecia areata, which were originally filed by Bioniz prior to our acquisition of the EQ101 asset.

Before obtaining marketing approval from the FDA 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 may require us to conduct additional preclinical studies of our existing or any future product candidates before it allows us to initiate clinical trials under any IND, 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 trials could significantly affect our product development costs. We do not know whether our ongoing and future trials will be completed on schedule, if at all, or whether our trials will begin on time, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- impacts and risks associated with global health epidemics such as those related to COVID-19 (for example, in March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, we decided to pause enrollment in our Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis), which enrollment was resumed in July 2020);

- the FDA disagreeing as to the design or implementation of our clinical studies;
- obtaining FDA authorizations to commence a trial or reaching a consensus with the FDA on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- additional nonclinical pharmacology and toxicology studies to support Phase 2 and 3 trials;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up. As a result of impacts associated with the COVID-19 pandemic, we have observed slower-than-expected enrollment rates in our clinical trials;
- subjects choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials 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;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- us, or our contractors not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol; 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 trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or by other regulatory agencies or health authorities that have jurisdiction in countries in which the trial is being conducted. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory 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 trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Certain of our scientific advisors or consultants who receive compensation from us are likely to be investigators for our future clinical trials. 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 study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial 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 itolizumab (EQ001) in one or more indications. If we experience delays in the completion of, or termination of, any clinical trial of itolizumab (EQ001), the commercial prospects of itolizumab (EQ001) will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues 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 trials, 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 trials for itolizumab (EQ001) if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. Multiple factors could contribute to such challenges of enrolling our clinical trials, including impacts related to the COVID-19 pandemic, which have already adversely impacted enrollment across all three of our current clinical trials. In particular, enrollment in our Phase 1b clinical trial in uncontrolled asthma was slower-than-expected due to disruptions to operations at clinical trial sites in Australia related to the COVID-19 pandemic as well as due to patients' high-risk status for COVID-19 and a decrease in asthma exacerbations as a result of stay-at-home and social distancing measures. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as itolizumab (EQ001), and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. This is acutely relevant for our development of itolizumab (EQ001) for the treatment of patients with uncontrolled moderate to severe asthma and lupus nephritis, each diseases for which there is significant competition for clinical trial subjects. Patient enrollment is also affected by other factors, including:

- impacts and risks associated with global health epidemics such as those related to COVID-19;
- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- invasive procedures required to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- perceived risks and benefits;
- efforts to facilitate timely enrollment in clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and retain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in

increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

The novel coronavirus global pandemic has adversely impacted our business, including our clinical trials, and could further impact other aspects of our business including our supply chain, personnel, and our business development activities, the magnitude and extent of which are uncertain

In December 2019, a novel strain of coronavirus, designated COVID-19, was first reported in Wuhan, China and has since become a global pandemic. The President of the United States declared the coronavirus pandemic a national emergency and many states and municipalities in the United States, including California, have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions). As a result, we have implemented work-from-home policies for employees and have moved to a "virtual" model with respect to our partner support activities. The effects of government actions and our policies and those of third parties to reduce the spread of the coronavirus may negatively impact productivity, cause disruptions to our supply chain and ongoing and future clinical trials and impair our ability to execute our business development strategy. These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to the coronavirus or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our clinical trials. In particular, certain of our service providers involved in clinical trials are located in regions that have been subject to coronavirus-related actions and policies that limit the conduct of normal business operations. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the coronavirus, our ability to continue advancing development of our product candidates may become impaired.

In addition, our clinical trials have been and may continue to be affected by the coronavirus. In March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, we decided to pause enrollment in our Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis. This decision was not based on any observed safety issues associated with itolizumab (EQ001) but rather out of an abundance of caution related to the current global pandemic and our concern for the well-being of patients and their caregivers. In July 2020, we announced that patient enrollment in both of those trials had resumed. We did not pause enrollment of patients in the Phase 1b/2 clinical trial of itolizumab (EQ001) for the treatment of aGVHD given the acute life-threatening severity of the disease as we believe itolizumab (EQ001) represents a potentially life-saving treatment for these severely ill patients. However, there remains a significant risk that enrollment of all of our active clinical trials and the timing of data from those trials may be adversely impacted by the COVID-19 pandemic. Clinical site initiation and patient enrollment in our current and future clinical trials may be delayed due to prioritization of hospital resources toward the coronavirus. Patients in our ongoing or planned clinical trials may also choose to not enroll, not participate in follow-up clinical visits or drop out of the trial as a precaution against contracting the coronavirus. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to the coronavirus, may be adversely impacted. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

The spread of the coronavirus and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the coronavirus may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position.

Despite recent progress in the administration of vaccines, the extent to which the outbreak of recent variants, including Delta and Omicron, and the related containment and mitigation measures that have been put into place across the globe, may impact our clinical trials, our supply chain, our access to capital and our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the pandemic, the duration of the pandemic and the efforts by governments and business to contain it, business closures or business disruptions and the impact on the economy and capital markets.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, 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 trials as well as in clinical trials, investigator-initiated studies, or off-label usage in jurisdictions where itolizumab is available commercially.

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 subcutaneous 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 or ALZUMAb-L in their own sponsored clinical trials, off-label use, investigator-initiated trials, or third party-sponsored trials over which we have no control. 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 trials 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 trials by us or the FDA for a number of reasons. Additionally, a material percentage of patients in our ongoing aGVHD clinical trial 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 trial, 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 trials 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 trials 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 trials. 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 trials, 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 trials, as well as conditions that did not occur or went undetected in previous trials, 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 trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our 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 or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same 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 clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between 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 trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular 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 for, and commercialize, itolizumab (EQ001) or any future product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

In the past, we have conducted clinical trials of itolizumab (EQ001) outside of the United States, and we plan to utilize sites outside of the United States for other clinical trials of itolizumab (EQ001), including our Phase 3 pivotal study in aGVHD, as well as possibly for clinical trials of our other product candidates. The FDA may not accept data from such trials, 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 trial of itolizumab (EQ001) in healthy subjects in Australia to assess the safety and tolerability of the subcutaneous version of itolizumab (EQ001). The trial also included a separate stage to compare the pharmacokinetics of the intravenous administration of itolizumab (EQ001) to ALZUMAb and determine the absolute bioavailability of subcutaneous 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 trials for the treatment of aGVHD and lupus nephritis. 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 trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

We conducted a Phase 1b, multiple ascending dose, clinical trial of itolizumab (EQ001) in uncontrolled moderate to severe asthma at sites in Australia and New Zealand. Also, we plan to utilize sites outside of the United States in our Phase 3 pivotal study in aGVHD, as well as potentially in our clinical studies of our other product candidates. Although the FDA may accept data from clinical trials conducted entirely outside the United States and not under an IND, acceptance of such study data is generally subject to certain conditions. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when 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 trial was inadequate, which would likely require us to conduct additional clinical trials. Conducting clinical trials 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 itolizumab (EQ001) in the future. We may expend our limited resources to pursue a particular indication for itolizumab (EQ001) and fail to capitalize on 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 itolizumab (EQ001) may have therapeutic benefit, yet this may fail to yield additional clinical development opportunities for itolizumab (EQ001) for a number of reasons, including, itolizumab (EQ001) 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 itolizumab (EQ001) 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 itolizumab (EQ001) development on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other indications or for any future 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 on itolizumab (EQ001) for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for itolizumab (EQ001) or any future product candidate, 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 for itolizumab (EQ001) or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, itolizumab (EQ001) and any future 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 that we receive for itolizumab (EQ001) or any future 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 trials, 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 trials 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 trials;
- fines, warning letters or holds on clinical trials;
- 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 itolizumab (EQ001) or any future 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, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.

If itolizumab (EQ001) or any of our product candidates receives 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 itolizumab (EQ001) or any other 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 itolizumab (EQ001) or 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 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.

We are aware that other products addressing the same indications as itolizumab (EQ001), EQ101 and EQ102 are in development, and some have been approved. With regards to aGVHD, we are aware of both private and public companies with development programs, including CSL Behring LLC, ElsaLys Biotech, Xenikos B.V., Humanigen, Inc., Maat Pharma SA and AltruBio, Inc., and that Incyte has an approved product in steroid-refractory aGVHD. We are aware of a number of public companies with development programs targeting lupus nephritis including Bristol-Myers Squibb Company, Novartis AG, Boehringer Ingelheim GmbH, Genentech Inc., Kezar Life Sciences, Inc., AstraZeneca plc, Janssen Pharmaceuticals, Alexion Pharmaceuticals, Inc. and Omeros Corporation, and that both Aurinia Pharmaceuticals Inc. and GlaxoSmithKline plc have approved products in this indication. There are no approved products for alopecia areata or celiac disease. Private and public companies involved in alopecia areata drug development include Concert Pharmaceuticals, Eli Lilly and Company, Pfizer Inc., Reistone Biopharma and Arena Pharmaceuticals (acquired by Pfizer in 2022). Private and public companies with development programs targeting celiac disease, include 9 Meters Biopharma, Takeda Pharmaceuticals, Zedira, Provention Bio, GlaxoSmithKline plc, Selecta Biosciences and ImmunogenX.

Many of our competitors, such as large pharmaceutical and biotechnology companies like Amgen Inc. and Bristol-Myers Squibb Company, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, 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 trial sites and patient registration for clinical trials, 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 trials 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 trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, itolizumab (EQ001) or any future programs.

The key competitive factors affecting the success of itolizumab (EQ001) are likely to be its 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.

Itolizumab (EQ001) 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, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the 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 trials 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 the U.S. market opportunities for itolizumab (EQ001) 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 immuno-inflammatory diseases, with an initial intention to develop it for the treatment of patients with aGVHD, lupus nephritis and uncontrolled moderate to severe asthma. Our projections of addressable patient populations in the Equillium Territory that have the potential to benefit from treatment with itolizumab (EQ001) are based on estimates and may prove to be incorrect. If any of our estimates are inaccurate, the market opportunities for itolizumab (EQ001) 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 itolizumab (EQ001).

We received orphan drug designations for itolizumab (EQ001) 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 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 lupus nephritis. 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 itolizumab (EQ001) due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell itolizumab (EQ001) or any future product candidates profitably.

Obtaining coverage and adequate reimbursement approval for 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 itolizumab (EQ001) or other future 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 itolizumab (EQ001), such tests will be subject to the coverage and reimbursement process separate and apart from the coverage and reimbursement we seek for our itolizumab (EQ001).

We expect to experience pricing pressures in connection with the sale of itolizumab (EQ001) or any future 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. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Risks Related to Manufacturing and Our Reliance on Third Parties

The manufacture of biologics is complex and Biocon, our exclusive manufacturer of itolizumab, may encounter difficulties in production, distribution and delivery of itolizumab. If Biocon encounters such difficulties, our ability to provide supply of itolizumab (EQ001) for clinical trials, 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 Biocon to fulfill our clinical and commercial supply of itolizumab (EQ001). 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. However, the process of manufacturing biologics is complex, highly-regulated and subject to multiple risks. Manufacturing biologics 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 trials, 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 for itolizumab (EQ001), the production, distribution and delivery of biologics is also subject to the laws and regulations of the country. Any changes in the laws and regulations of another country could delay clinical trials, 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 trials 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 for itolizumab (EQ001) or any future product candidates, there is no assurance that Biocon or other potential manufacturers 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 such as the recent COVID-19 outbreak. If our manufacturers are unable to produce sufficient quantities for clinical trials 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 a biologic manufacturing process is a difficult and uncertain task, and Biocon 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 itolizumab (EQ001) (or other biologics) or meet product demand. 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 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 trials, 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 can be lengthy and involve significant additional costs. Even if we are able to adequately validate and scale-up the manufacturing process for itolizumab (EQ001) 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 will 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 contracted research organizations (CROs) to conduct our clinical trials 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 trials ourselves. As a result, we are and will be dependent on third parties to conduct our ongoing and future clinical trials of itolizumab (EQ001) and preclinical studies, and any future preclinical studies and clinical trials of any other product candidates. The timing of the initiation and completion of these trials 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 trials 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 trial 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. 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 trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials 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 trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely 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 trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trial 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 trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial 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 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 trials 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 trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for 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.

We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to 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 itolizumab (EQ001) and any future product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with biotechnology companies for the development and potential commercialization of product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other 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 a product candidate, 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 trials;
- 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.

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 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 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 itolizumab (EQ001) and others, 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 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 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 trials 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 defend 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 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 trial 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 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 itolizumab (EQ001) 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 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 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 itolizumab 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 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 trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring 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 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. 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 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 trials 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. 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. 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, 2021, we had 45 full-time employees. As we advance itolizumab (EQ001) in clinical development and conduct research and development of the Bioniz assets, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs and, if itolizumab (EQ001) or any future product candidates receive marketing approval, 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 trials for itolizumab (EQ001), EQ101, EQ102 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 itolizumab (EQ001) and any future 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 and other contract service providers, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our ongoing and future clinical trials and the manufacture of 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 trials 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 itolizumab (EQ001) and any future 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 in the Greater San Diego Area and the San Francisco Bay Area regions that are 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 itolizumab (EQ001) or any future 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. In addition to the topics typically considered in such reviews, in our industry, the public's ability to access our medicines is of particular importance.

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 trial 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 trial 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 trials, 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.

Our internal information technology systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

In the ordinary course of our business, we may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information).

We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. 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. We may share or receive sensitive information with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, and personnel (such as through theft or misuse). Threat actors, personnel, sophisticated nation-states, and nation-state-supported actors now engage and are expected to continue to engage in cyberattacks, including for geopolitical and/or military reasons. Specifically, due to the political uncertainty and military actions involving Russia, Ukraine, and surrounding regions, we and the third parties upon which we rely may be vulnerable to a heightened risk of

cyberattacks 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 may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through 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, personnel misconduct or error, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data 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.

Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products and services) or the third-party information technology systems that support us and our services. Furthermore, the COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. 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 trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. There can be no assurance that the security measures we and our third-party suppliers have implemented will be effective. We are not always able to detect vulnerabilities in our security controls, systems, or software (including third-party software we have installed on our systems) because such threats and techniques change frequently and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Efforts to identify and remediate vulnerabilities, if any, in our information technology systems or software (including third-party software we have installed on our systems) may not be successful.

Applicable data privacy and security obligations may require us to notify relevant stakeholders 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. These consequences may include: 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; interruptions in our operations (including the delay of development and commercialization of itolizumab (EQ001) or any future product candidates); financial loss; and other similar harms. Security incidents and attendant consequences may 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.

We are subject to stringent and changing 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; 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.

In the ordinary course of business, we process sensitive information, along with data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state

data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial 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 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.

Additionally, the California Consumer Privacy Act of 2018 ("CCPA") imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation) and a private right of action for certain breaches. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020 ("CPRA"), effective January 1, 2023, will expand the CCPA. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area ("EEA") that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of "Standard Contractual Clauses" ("SCCs") that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data.

In addition, the UK similarly restricts personal data transfers outside of those jurisdictions to countries, such as the United States, that do not provide an adequate level of personal data protection, and certain countries outside Europe (e.g. China) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. 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 significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail to do so (or be perceived to have failed to have done so). Moreover, despite our efforts, our personnel or third parties upon whom we

rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Any of these events could have a material 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 trials); 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 revision or restructuring of our operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2021, we had aggregate U.S. federal net operating loss, or NOL, carryforwards of approximately $86.4 million. Our U.S. federal NOLs generated in taxable years beginning before January 1, 2018 could expire unused. Under current U.S. federal income tax law, U.S. federal NOLs generated in taxable years beginning after December 31, 2020, may be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in tax years beginning after December 31, 2017, 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, 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. It is possible that we have experienced one or more ownership changes in the past. In addition, 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 (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 conduct the clinical development of itolizumab (EQ001) for the treatment of uncontrolled asthma in Australia and New Zealand. 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 itolizumab (EQ001) in Australia and New Zealand, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidate 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, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, 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 trials 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 trials for itolizumab (EQ001) 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 future clinical trials 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. The Affordable Care Act, among other things: (i) introduced a "average manufacturer price" calculation for drugs and biologics that are inhaled, infused, instilled, implanted or injected and that are not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (v) established Medicare Part D coverage gap discount program, in which manufacturers currently must agree to offer 70% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) created a licensure framework for follow-on biologic products; and (viii) established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act

of 2017, or TCJA, was enacted, which included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court held in a 7-2 opinion that the states and individuals challenging the constitutionality of Affordable Care Act do not have standing to challenge the law. The U.S. Supreme Court did not reach the merits of the challenge regarding Affordable Care Act's constitutionality, but the decision ended the case. 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. 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 through 2031 unless additional Congressional action is taken. COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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 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, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempt to implement several of the Trump administration proposals. The FDA concurrently released a final rule and guidance in September 2020 implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed by the Infrastructure Investment and Jobs Act until January 1, 2026. In addition, on November 20, 2020, the Center for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. 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. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. 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

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. It is possible that additional governmental action is taken in response to the COVID-19 pandemic. 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 recent 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. Given AB 5's recent passage, there is little guidance from the regulatory authorities charged with its enforcement 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, physicians 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 CMS 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 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 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 receive 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 trials 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;
- delays or other adverse impacts to our clinical trials from global health epidemics, such as those related to COVID-19;
- our ability to enroll and retain subjects in our ongoing and future clinical trials;
- results from our ongoing and future clinical trials with our current and future product candidates, and the results of the clinical trials of our competitors or of Biocon;
- adverse events observed in our clinical trials or in the clinical trials, exploratory studies, or other clinical uses of itolizumab supported by Biocon or third parties or during post-approval use of itolizumab;
- the timing of topline data from ongoing trials, including our ongoing and planned clinical trials of itolizumab;
- 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 in the United States and other countries 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 trial results, regulatory developments, acquisitions, 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; 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 and conflict in Ukraine, that have affected and 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, collaboration and license agreements. 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 July 2020, we entered into the 2020 ATM Facility with Jefferies under which we may offer and sell shares of our common stock having an aggregate offering price of up to $150 million from time to time through Jefferies acting as our sales agent. As of December 31, 2021, we have sold an aggregate of 788,685 shares of our common stock under the 2020 ATM facility for gross proceeds of $10.4 million. There have been no sales of shares of our common stock under the 2020 ATM Facility since December 31, 2021 and through the date of the filing of this Annual Report on Form 10-K.

In March 2020, we entered into the Purchase Agreement with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $15.0 million of shares of our common stock, from time to time over the 36-month term of the Purchase Agreement, and we issued an additional 65,374 shares of our common stock to Lincoln Park as commitment shares under the Purchase Agreement. As of the date of the filing of this Annual Report on Form 10-K, we have not sold any shares of our common stock to Lincoln Park under the Purchase Agreement.

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. Subject to limited exceptions, our Loan Agreement also prohibits us from incurring indebtedness without the prior written consent of the lenders.

If we raise funds through collaboration and license agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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.

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 18, 2022, we had 34,275,898 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 and various vesting agreements. 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.

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 trial 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 Securities Exchange Act of 1934, as amended, or 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 Global 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 may be adversely affected by earthquakes, fires, other natural disasters, or other sudden, unforeseen and severe adverse events, including public health events, 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 events such as the COVID-19 pandemic 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 trials, 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 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 trials, 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 itolizumab (EQ001) and any future product candidates in human clinical trials 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 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 trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial 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 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 itolizumab (EQ001) and any future product candidates advance through clinical trials 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 Internal Revenue Code of 1986, as amended. 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. For example, 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, Congress and the Biden administration have recently proposed legislation (which has not yet been enacted) to make various tax law changes, including to increase U.S. taxation of international business operations and impose a global minimum tax. While it is too early to predict the outcome of these proposals and they are subject to change, if enacted, they could have a material effect on out income tax liability. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act or any newly enacted federal tax legislation. 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 and the CARES Act 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.

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 an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering (i.e. December 31, 2023), (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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, including due to limitations that are currently imposed by our Loan Agreement. 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 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 San Diego, California, as well as office space in South San Francisco under leases with various expiration dates, with the latest extending through February 2027.

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. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of March 18, 2022, there were approximately 34 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, including due to limitations that are currently imposed by our Loan Agreement. 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 2022 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

None.

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 initial product candidate, itolizumab (EQ001), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6. CD6 plays a central role in the modulation of effector T cell, or T_{eff} cell, activity and trafficking, which drives a number of immuno-inflammatory diseases across multiple therapeutic areas. Therefore, we believe itolizumab (EQ001) may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.

In February 2022, we expanded our pipeline of novel immunomodulatory drug candidates, adding two first-in-class clinical stage assets, EQ101 and EQ102, and a proprietary product discovery platform, through the acquisition of Bioniz Therapeutics, Inc., or Bioniz, a privately held, clinical stage biotechnology company. Lead assets acquired are specific multi-cytokine inhibitors of key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immune-inflammatory indications.

This novel and differentiated pipeline of first-in-class immunology assets has the potential to address unmet medical needs in numerous areas, including transplant science, hematology, dermatology, gastroenterology, rheumatology, oncology and pulmonology.

Our pipeline is focused on developing itolizumab (EQ001), EQ101 and EQ102 as potential best-in-class, disease modifying treatments for multiple severe immuno-inflammatory disorders. We currently have active clinical development programs for itolizumab (EQ001) for the treatment of acute graft-versus-host disease, or aGVHD and lupus/lupus nephritis. In the fourth quarter of 2021, we completed a Phase 1b study of itolizumab (EQ001) in patients with uncontrolled asthma and met our primary objective of safety and tolerability. However, as a result of the ongoing pandemic and associated challenges conducting asthma trials, we decided to prioritize our clinical development efforts of itolizumab (EQ001) in our ongoing programs in aGVHD and lupus/lupus nephritis and will be reassessing our potential future development strategy in asthma. We are in the process of planning for the clinical development of EQ101 and EQ102 and currently expect to initiate a Phase 2 study of EQ101 in alopecia areata and a Phase 1 study of EQ102 in celiac disease, both in the second half of 2022.

We have ongoing translational biology programs to assess the therapeutic utility of itolizumab (EQ001) in additional indications where CD6 and its ligand, activated leukocyte cell adhesion molecule (ALCAM), play an important role in the pathogenesis of T cell mediated diseases. In addition, through the acquisition of Bioniz, we now also 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. 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 INDs, conducting clinical development of itolizumab (EQ001), acquiring new assets, and the general and administrative activities associated with operating a public company. Furthermore, in connection with the acquisition of Bioniz, we have expanded our pipeline from one product candidate to three 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 not generated any revenue from product sales or otherwise. Since inception, we have primarily financed our operations through our initial public offering, or IPO, a follow-on public offering, a registered direct offering, private placements of convertible promissory notes, term loans and sales of our common stock through "at-the-market" sales agreements, or ATM offerings, with Jefferies LLC, or Jefferies. We have incurred losses since our inception. For the years ended December 31, 2021 and 2020, our net losses were $39.1 million and $29.8 million, respectively. As of December 31, 2021, we had an accumulated deficit of $110.0 million. Substantially all of our operating

losses resulted from expenses incurred in connection with our research and development activities, non-clinical and clinical activities 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 itolizumab (EQ001), potentially expand the indications in which we conduct clinical development of itolizumab (EQ001), potentially acquire additional products and/or product candidates, seek regulatory approval for and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, incur increasing expense associated with our outstanding debt, and incur general corporate costs. We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2021, will enable us to fund our currently planned operations for at least the next 12 months.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for itolizumab (EQ001) or any future product candidate, 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. 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 COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates 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. In addition, subject to limited exceptions, our loan and security agreement with Oxford Finance LLC and Silicon Valley Bank also prohibits us from incurring indebtedness without the prior written consent of the lenders, which consent may be withheld at their sole and absolute discretion. 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

We currently have no products approved for sale, and we have not generated any revenues to date. In the future, we may generate revenue from collaboration or license agreements we may enter into with respect to our product candidates, 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 itolizumab (EQ001) and any future product candidates. If we fail to complete the development of 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.

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our non-clinical research and clinical development of itolizumab (EQ001). Our research and development expenses include:

- salaries and other related costs, including stock-based compensation and benefits, for personnel in research and development functions;
- 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 (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 itolizumab (EQ001), potentially expand the number of indications for which we are developing itolizumab (EQ001), and as we conduct research and development related to the recently acquired product candidates EQ101 and EQ102. The successful development of any of our product candidates is highly uncertain. At this time, due to the inherently unpredictable nature of pre-clinical and clinical development, which has been further exacerbated by the uncertain magnitude, extent and duration of impacts associated with the COVID-19 pandemic, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of itolizumab (EQ001) or the period, if any, in which material net cash inflows from itolizumab (EQ001) or from any of our other product candidates may commence. Clinical development timelines, the probability of success, and development costs can differ materially from expectations.

Completion of clinical trials 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 trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- managing the impact of COVID-19 pandemic and related precautions on the operation of our clinical trials;
- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites and the number of countries included in our clinical trials;
- the length of time required to enroll suitable patients;
- the inefficiencies and additional costs related to any delays and potential restarts of clinical trials;
- the number of doses that patients receive;
- the number of patients that participate in our clinical trials;
- the drop-out or discontinuation rates of patients in our clinical trials;
- 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 trials;
- the costs of procuring drug product for our clinical trials;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

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 outstanding 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 net foreign currency transaction losses and gains related to our Australian subsidiary.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table sets forth our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020	Change
Research and development	$ 26,379	$ 19,384	$ 6,995
General and administrative	11,407	10,164	1,243
Interest expense	(1,073)	(1,099)	26
Interest income	57	476	(419)
Other (expense) income, net	(250)	358	(608)

Research and Development Expenses

Research and development expenses were $26.4 million for the year ended December 31, 2021, compared to $19.4 million for the year ended December 31, 2020. The increase in research and development expense primarily includes the following changes:

- $3.4 million increase in employee compensation and benefits, primarily related to increased headcount;
- $3.4 million increase in clinical development expenses, primarily driven by start-up expenses related to our EQUATOR study, a lower Tax Incentive benefit from the Australian Taxation Office, higher costs associated with our EQUATE, EQUIP, and EQUALISE studies, partially offset by lower costs related to a Phase 3 COVID-19 clinical trial that we decided in 2020 not to commence;
- $0.4 million increase in overhead expenses primarily driven by higher recruiting expenses and the expansion of our laboratory operations; offset by
- $0.2 million decrease in consulting expenses.

General and Administrative Expenses

General and administrative expenses were $11.4 million for the year ended December 31, 2021, compared to $10.2 million for the year ended December 31, 2020. The increase in general and administrative expense primarily includes the following changes:

- $1.8 million increase in employee compensation and benefits, primarily related to increased headcount;
- $0.1 million increase in overhead expenses; offset by
- $0.5 million decrease in corporate consulting expenses; and
- $0.2 million decrease in legal and professional expenses

Interest Expense

Interest expense was $1.1 million for the years ended December 31, 2021 and 2020. Interest expense consists of interest on our term notes payable which had a consistent interest rate for 2021 and 2020.

Interest Income

Interest income was $0.1 million for the year ended December 31, 2021, as compared to $0.5 million for the year ended December 31, 2020. The decrease in interest income was primarily due to lower interest rates on our short-term investments during 2021 compared to 2020.

Other (Expense) Income, Net

Other expense, net was $0.3 million for the year ended December 31, 2021, compared to $0.4 million of other income, net for the year ended December 31, 2020. The change during 2021 compared to 2020 was primarily driven by increases in net foreign currency transaction losses.

Liquidity and Capital Resources

From inception through December 31, 2021, we raised an aggregate of approximately $178.1 million in gross proceeds pursuant to our IPO, follow-on public offering, private placements of convertible promissory notes, proceeds from term loans and proceeds from equity issuances under our ATM facility. As of December 31, 2021, we had $50.4 million in cash and cash equivalents and $30.3 million in short-term investments.

Sources of Liquidity

Registered Direct Offering

In February 2021, we entered into a securities purchase agreement with two institutional investors relating to the issuance and sale of an aggregate of 4,285,710 shares of common stock and warrants to purchase 1,285,713 shares of common stock for aggregate gross proceeds to us from this offering of approximately $30.0 million, excluding any proceeds we may receive upon exercise of the warrants. No underwriter or placement agent participated in the offering. The warrants are exercisable immediately upon issuance at an initial exercise price of $14.00 per share and are exercisable on a cashless basis. The warrants expire on the earlier of (i) the fifth anniversary of issuance or (ii) the 15th calendar date following the date on which we close upon an equity financing that results in not less than $25 million in gross proceeds to us at a price per share of common stock equal to or greater than $25.00, at which time, all remaining warrants will automatically exercise on a cashless basis.

Follow-on Public Offering

In August 2020, we completed an underwritten public offering of 5,461,169 shares of common stock at $7.00 per share, which included 461,169 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. We received gross proceeds from this offering totaling $38.2 million. Net proceeds from this offering, net of underwriting discounts and related issuance costs, were $35.7 million.

2020 Purchase Agreement

In March 2020, we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell

to Lincoln Park up to $15.0 million of shares of our common stock from time to time over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 65,374 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. We have not sold any shares of our common stock to Lincoln Park under the Purchase Agreement through the date of the filing of this Annual Report on Form 10-K.

At-the-Market Offering Program

In November 2019, we entered into an Open Market Sales Agreement℠ with Jefferies to sell shares of our common stock having aggregate sales proceeds of up to $8.45 million, from time to time, through an ATM equity offering program under which Jefferies acts as sales agent, or the 2019 ATM Facility. Under the 2019 ATM Facility, we set certain parameters for the sale of shares, which may include but are not limited to the number of shares to be issued, the time period during which sales are requested to be made, and any minimum price below which sales may not be made. Jefferies was entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. As of December 31, 2020, the 2019 ATM Facility had been fully utilized. We sold an aggregate of 943,739 shares of our common stock under the 2019 ATM Facility for gross proceeds of $8.45 million.

On July 14, 2020, we entered into another Open Market Sales Agreement with Jefferies for a new ATM equity offering to sell shares of our common stock, from time to time, having aggregate sales proceeds of up to $150 million under which Jefferies would act as sales agent, or the 2020 ATM Facility. The 2020 ATM Facility provides that Jefferies is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. We are not obligated to make any sales under the 2020 ATM Facility. As of December 31, 2021, we sold an aggregate of 788,685 shares of common stock under the 2020 ATM Facility, for gross proceeds of $10.4 million. We paid cash commissions on the gross proceeds, plus reimbursement expenses to Jefferies, legal fees and other issuance costs in the aggregate amount of $0.4 million, resulting in net proceeds of $10.0 million. There have been no further sales of shares under the 2020 ATM Facility through the date of the filing of this Annual Report on Form 10-K

September 2019 Loan Agreement

In September 2019, we entered into a loan and security agreement, or Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or together, the Lenders, pursuant to which we can borrow up to $20.0 million in a series of term loans. Upon entering into the Loan Agreement, we borrowed $10.0 million, or the Term Loan. As of December 31, 2020, we were no longer eligible to receive the additional funding up to $10.0 million under the Loan Agreement.

The Term Loan matures on June 1, 2024, or the Maturity Date, and is repaid through interest-only payments through June 30, 2021, followed by 36 equal monthly payments of principal and interest. The Term Loan bears interest 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 precedes the month in which the interest will accrue, plus (b) 3.00%.

On December 18, 2020, we entered into the First Amendment to the Loan Agreement, or the First Amendment, with the Lenders whereby if we achieved positive topline data in either our (a) Phase 1b aGVHD trial of itolizumab (EQ001) or (b) Phase 1b asthma trial of itolizumab (EQ001), supporting a formal decision to advance into Phase 2 development, and as confirmed by our Board of Directors, on or prior to June 30, 2021, the interest-only payments would be automatically extended through December 31, 2021.

On April 23, 2021, we entered into the Second Amendment to the Loan Agreement, or the Second Amendment, which added two new milestones: (i) we achieve positive data in our Phase 1b aGVHD trial of itolizumab (EQ001) supporting a formal decision to advance into Phase 2 or Phase 3 development, and as confirmed by our Board of Directors in written board minutes, or the Interest-Only Extension Milestone, and (ii) we initiate a pivotal Phase 3 aGVHD trial, or the Interest-Only Extension II Milestone. If we achieve the Interest-Only Extension Milestone on or prior to June 30, 2021, then interest-only payments will be automatically extended through June 30, 2022. If we achieve the Interest-Only Extension II Milestone on or prior to June 30, 2022, then interest-only payments will be automatically extended through September 30, 2022. The Second Amendment also amended the final payment percentage from 4.5% to 5.0%.

In February 2022, we entered into the Third Amendment to the Loan Agreement (the Third Amendment) which added Bioniz Therapeutics, Inc. as a secured party to the loan.

In May 2021, we achieved the Interest-Only Extension Milestone. Due to the achievement of the Interest-Only Extension Milestone, the interest-only payments were extended through June 30, 2022, followed by 24 equal monthly principal payments and interest. In March 2022, we obtained confirmation from Lenders that the Interest-Only Extension II milestone had been achieved, which further extends the interest-only payments through September 30, 2022.

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 itolizumab (EQ001), including potential new indications, and as we conduct research and development activities related to the Bioniz assets. We expect that our primary uses of capital will be for clinical research and development services, preclinical research, manufacturing, legal and other regulatory compliance expenses, compensation and related expenses, risk management, and general overhead costs.

We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2021 will enable us to fund our currently planned operations for at least the next 12 months. 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 trials is costly, and the timing of progress in these trials 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 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:

- the initiation, progress, timing, costs and results of our ongoing and future clinical trials of itolizumab (EQ001) and other product candidates, including as such activities may be adversely impacted by the ongoing COVID-19 pandemic and evolving conflict in Ukraine;
- the number and scope of indications we decide to pursue for the development of itolizumab (EQ001) and our other product candidates;
- the cost, timing and outcome of regulatory review of any Biologics License Application, or BLA, we may submit for our product candidates;
- the costs and timing of manufacturing itolizumab (EQ001) and other product candidates, if approved;
- 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;
- 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; and
- the cost associated with commercializing 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. 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 ongoing COVID-19 pandemic and actions taken to slow its spread, and more recently with the conflict in Ukraine, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates 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 $110.0 million as of December 31, 2021. We expect operating losses and negative cash flows to continue for at least the next several years as we continue to incur costs related to the development of itolizumab (EQ001) and our other product candidates.

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, 2021	Year Ended December 31, 2020
Net cash provided by (used in):		
Operating activities	$ (32,081)	$ (24,624)
Investing activities	27,406	(18,592)
Financing activities	31,061	53,945
Effect of exchange rate changes on cash	(2)	34
Net increase in cash and cash equivalents	$ 26,384	$ 10,763

Operating Activities

Net cash used in operating activities during the year ended December 31, 2021 primarily consisted of a net loss of $39.1 million adjusted for net non-cash expenses of $5.3 million and net changes in operating assets and liabilities of $1.7 million. The primary non-cash expense adjustment to net loss was stock-based compensation. The increase in net cash used in operating activities was primarily the result of the increase in operating expenses during the year ended December 31, 2021 related to the ramp up in our research and clinical development activities and increased headcount to support the growth of the company.

Net cash used in operating activities during the year ended December 31, 2020 primarily consisted of a net loss of $29.8 million adjusted for net non-cash expenses of $3.9 million and net changes in operating assets and liabilities of $1.3 million. The primary non-cash expense adjustment to net loss was stock-based compensation. The increase in net cash used in operating activities was primarily the result of the increase in operating expenses during the year ended December 31, 2020 related to the ramp up in our research and clinical development activities and increased headcount to support the growth of the company.

Investing Activities

Net cash provided by investing activities was $27.4 million during the year ended December 31, 2021. We purchased $33.0 million of short-term investments and $60.5 million of our short-term investments matured during the period. Purchases of property and equipment for the year ended December 31, 2021 totaled $0.1 million.

Net cash used in investing activities was $18.6 million during the year ended December 31, 2020. We purchased $55.5 million of short-term investments and $37.1 million of our short-term investments matured during the period. Purchases of property and equipment for the year ended December 31, 2020 totaled $0.2 million.

Financing Activities

Net cash provided by financing activities totaled $31.1 million during the year ended December 31, 2021. We received net proceeds from the sale of shares related to our registered direct offering totaling $29.9 million and proceeds from both the issuance of shares under our employee stock purchase plan and proceeds from the exercise of stock options totaling $1.2 million.

Net cash provided by financing activities totaled $53.9 million during the year ended December 31, 2020. We received net proceeds from the sale of shares related to our follow-on public offering totaling $35.7 million, net proceeds from the sale of shares under our ATM facilities totaling $18.1 million and proceeds from both the issuance of shares under our employee stock purchase plan and proceeds from the exercise of stock options totaling $0.2 million.

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 and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. 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.

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 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, 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, 2021, 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, 2021.

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 and principal financial 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, 2021, 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, 2021, 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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, 2021 and is incorporated in this Annual Report on Form10-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 section entitled "Security Ownership of Certain Beneficial Owners and Management" 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 section entitled "Transactions with Related Persons and Indemnification" 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 10.6 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.

10.6†	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 10.7 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.
10.7	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	Loan and Security Agreement, effective as of September 30, 2019, by and among the Registrant, Oxford Finance LLC and Silicon Valley Bank, 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 November 12, 2019.
10.15††	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.
10.16+	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.
10.17+	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.
10.18+	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.
10.19+	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.
10.20	Purchase Agreement, dated March 27, 2020, by and between the Registrant and Lincoln Park Capital Fund, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 30, 2020.
10.21	Open Market Sale Agreement, dated as of July 14, 2020, 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 July 14, 2020.

10.22+	Offer Letter, dated December 15, 2020, by and between the Registrant and Dolca Thomas, M.D., incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 21, 2020.
10.23*	First Amendment to Loan and Security Agreement by and between Registrant and Oxford Finance LLC, dated December 18, 2020.
10.24+	Amended and Restated Offer Letter, effective January 26, 2021, by and between the Registrant and Joel Rothman, incorporated by reference to Exhibit 10.28 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 24, 2021.
10.25*+	Amended and Restated Equillium, Inc. Non-Employee Director Compensation Policy.
10.26	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.
10.27	Second Amendment to Loan and Security Agreement by and between Registrant and Oxford Finance LLC, dated April 23, 2021, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 13, 2021.
10.28*	Third Amendment to Loan and Security Agreement by and between Registrant and Oxford Finance LLC, dated February 14, 2022.
10.29*	Confidential Separation Agreement and General Release of All Claims dated February 13, 2022, by and between Registrant and Dolca Thomas, M.D.
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.
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).

* Filed herewith.

** 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 portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

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 23, 2022

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 23, 2022
/s/ Jason A. Keyes Jason A. Keyes	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 23, 2022
/s/ Daniel M. Bradbury Daniel M. Bradbury	Chairman of the Board of Directors	March 23, 2022
/s/ Stephen Connelly, Ph.D. Stephen Connelly, Ph.D.	Member of the Board of Directors	March 23, 2022
/s/ Martha J. Demski Martha J. Demski	Member of the Board of Directors	March 23, 2022
/s/ Bala S. Manian, Ph.D. Bala S. Manian, Ph.D.	Member of the Board of Directors	March 23, 2022
/s/ Charles McDermott Charles McDermott	Member of the Board of Directors	March 23, 2022
/s/ Mark Pruzanski, M.D. Mark Pruzanski, M.D.	Member of the Board of Directors	March 23, 2022
/s/ Y. Katherine Xu, M.D. Y. Katherine Xu, M.D.	Member of the Board of Directors	March 23, 2022
/s/Barbara Troupin, M.D Barbara Troupin, M.D	Member of the Board of Directors	March 23, 2022

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 subsidiary (the Company) as of December 31, 2021 and 2020, 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, 2021 and 2020, 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 23, 2022

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

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 50,366	$ 23,982
Short-term investments	30,345	58,181
Prepaid expenses and other current assets	2,659	3,011
Total current assets	83,370	85,174
Operating lease right-of-use assets	1,645	-
Property and equipment, net	237	239
Other assets	153	15
Total assets	$ 85,405	$ 85,428
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,225	$ 2,766
Accrued expenses	5,886	2,813
Current portion of long-term notes payable	1,428	1,666
Current portion of operating lease liabilities	376	-
Total current liabilities	8,915	7,245
Long-term notes payable	8,750	8,275
Long-term operating lease liabilities	1,235	-
Other non-current liabilities	-	54
Total liabilities	18,900	15,574
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2021 and 2020; 29,455,668 and 24,753,102 shares issued and outstanding as of December 31, 2021 and 2020, respectively	2	2
Additional paid-in capital	176,618	141,074
Accumulated other comprehensive loss	(138)	(297)
Accumulated deficit	(109,977)	(70,925)
Total stockholders' equity	66,505	69,854
Total liabilities and stockholders' equity	$ 85,405	$ 85,428

See accompanying notes.

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

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating expenses:		
Research and development	$ 26,379	$ 19,384
General and administrative	11,407	10,164
Total operating expenses	37,786	29,548
Loss from operations	(37,786)	(29,548)
Other expense, net:		
Interest expense	(1,073)	(1,099)
Interest income	57	476
Other (expense) income, net	(250)	358
Total other expense, net	(1,266)	(265)
Net loss	$ (39,052)	$ (29,813)
Other comprehensive income (loss), net:		
Unrealized loss on available-for-sale securities, net	(59)	(41)
Foreign currency translation gain (loss)	218	(277)
Total other comprehensive income (loss), net	159	(318)
Comprehensive loss	$ (38,893)	$ (30,131)
Net loss per share, basic and diluted	$ (1.36)	$ (1.46)
Weighted-average number of common shares outstanding, basic and diluted	28,806,310	20,355,534

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	17,425,654	$ 1	$ 82,938	$ 21	$ (41,112)	$ 41,848
Issuance of common stock from follow-on offering, net of issuance costs	5,461,169	1	35,716	-	-	35,717
Issuance of common stock under ATM, net of issuance costs	1,714,174	-	18,115	-	-	18,115
Issuance of common stock	83,662	-	252	-	-	252
Issuance of common stock under employee stock purchase plan	65,443	-	156	-	-	156
Exercise of stock options	3,000	-	7	-	-	7
Vesting of restricted stock liability	-	-	73	-	-	73
Stock-based compensation expense	-	-	3,817	-	-	3,817
Comprehensive loss	-	-	-	(318)	-	(318)
Net loss	-	-	-	-	(29,813)	(29,813)
Balance at December 31, 2020	24,753,102	$ 2	$ 141,074	$ (297)	$ (70,925)	$ 69,854
Issuance of common stock under registered direct offering, net of offering costs	4,285,710	-	29,909	-	-	29,909
Exercise of stock options	326,454	-	891	-	-	891
Issuance of common stock under employee stock purchase plan	90,402	-	261	-	-	261
Vesting of restricted stock liability	-	-	73	-	-	73
Stock-based compensation expense	-	-	4,410	-	-	4,410
Comprehensive income	-	-	-	159	-	159
Net loss	-	-	-	-	(39,052)	(39,052)
Balance at December 31, 2021	29,455,668	$ 2	$ 176,618	$ (138)	$ (109,977)	$ 66,505

See accompanying notes.

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

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating activities:		
Net loss	$ (39,052)	$ (29,813)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	72	45
Stock-based compensation	4,410	3,817
Net unrealized loss (gain) on foreign currency transactions	240	(360)
Non-cash consulting expense	-	81
Amortization of term loan discount and issuance costs	237	260
Realized gain on investments	-	(13)
Amortization of investments, net	314	104
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	214	(491)
Right-of-use assets, operating leases	114	-
Accounts payable	(1,578)	894
Accrued expenses	3,099	852
Operating lease liabilities	(151)	-
Net cash used in operating activities	(32,081)	(24,624)
Investing activities:		
Purchases of property and equipment	(57)	(202)
Purchases of short-term investments	(32,992)	(55,510)
Maturities of short-term investments	60,455	37,120
Net cash provided by (used in) investing activities	27,406	(18,592)
Financing activities:		
Proceeds from registered direct offering, net of offering costs	29,909	-
Proceeds from issuance of common stock from follow-on offering, net of issuance costs	-	35,717
Proceeds from issuance of common stock under ATM, net of issuance costs	-	18,065
Proceeds from exercise of stock options	891	7
Proceeds from ESPP purchases	261	156
Net cash provided by financing activities	31,061	53,945
Effect of exchange rate changes on cash and cash equivalents	(2)	34
Net increase in cash and cash equivalents	26,384	10,763
Cash and cash equivalents at beginning of period	23,982	13,219
Cash and cash equivalents at end of period	$ 50,366	$ 23,982
Supplemental cash flow information:		
Cash paid for interest	$ 836	$ 839
Right-of-use assets obtained in exchange for lease obligations	$ 1,759	$ -
Amounts included in accounts payable for purchases of property and equipment	$ 14	$ -
Issuance of commitment shares to Lincoln Park pursuant to agreement	$ -	$ 171

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 deep understanding of immunology to develop novel products to treat severe autoimmune and inflammatory disorders with high unmet medical need.

From inception through December 31, 2021, 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 initial product candidate, itolizumab (EQ001), conducting business development activities, and the general and administrative activities associated with operating a public company. In addition, the Company has not generated revenues from its principal operations and the sales and income potential of its business is unproven.

Liquidity and Business Risks

As of December 31, 2021, the Company had $80.7 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 to fund research and development of itolizumab (EQ001), for potentially acquiring and conducting research and development of new products, and for working capital and other general corporate purposes. 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 itolizumab (EQ001) or any future product candidate, 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. 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 COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates 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, 2021 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).

The COVID-19 outbreak in the United States and the rest of the world has caused disruptions to the Company's business, which may delay results of the Company's clinical trials and adversely impact the Company's business. The Company cannot predict how legal and regulatory responses to concerns about COVID-19 or other major public health issues will impact the Company's business, nor can it predict potential adverse impacts related to the availability of capital to fund the Company's operations. Additionally, the Company's workforce and outside consultants may also be affected, which could result in an adverse impact on the Company's ability to conduct business. Any of these factors, alone or in combination with others, could harm the Company's business, results of operations, financial condition or liquidity. However, the magnitude, timing, and duration of any such potential financial impacts cannot be reasonably estimated at this time.

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).

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary in Australia. 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 loss 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. Realized and unrealized gains and losses denominated in foreign currencies are recorded in operating expenses in the Company's consolidated statements of operations. For the years ended December 31, 2021 and 2020, net realized and unrealized gain totaled $0.2 million and, net realized and unrealized loss of $0.3 million, respectively.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which supersedes ASC 840, *Leases*. ASU 2016-02 establishes ASC 842, *Leases*, and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification determines whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases. The Company adopted ASU 2016-02 and ASC 842 using the modified retrospective approach with an effective date of January 1, 2021. Periods prior to January 1, 2021 have not been restated for the adoption of ASC 842 and continue to reflect the accounting treatment of leases in accordance with ASC 840. In connection with the adoption, the Company elected the package of practical expedients to not reassess prior conclusions about lease identification, lease classification and capitalized indirect costs. The Company did not elect the use of hindsight practical expedient. Upon adoption, effective January 1, 2021, the Company recognized operating lease right-of-use assets of $0.5 million and operating lease liabilities of $0.5 million.

In December 2019, the FASB issued ASU No. 2019-12, I*ncome Taxes (Topic 740)*: Simplifying the Accounting for Income Taxes. The amendments in this ASU simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are effective for the Company on January 1, 2021. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements not adopted

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments*, which will require a reporting entity to use a new forward-looking impairment model for most financial assets that generally will result in the earlier recognition of allowances for losses. The ASU, along with related amendments, revised the measurement of credit losses for financial assets measured at amortized cost from an incurred loss to an expected loss methodology. The ASU affected receivables, debt securities, net investment in leases, and most other financial assets that represent a right to receive cash. The standard and other related subsequently issued ASUs will be effective for the Company for annual periods beginning after December 15, 2022, with early adoption permitted beginning in 2019. The Company is currently evaluating the impact that the adoption of the standard and other related subsequently issued ASUs will have on its consolidated financial statements and accompanying footnotes.

Other accounting standard updates effective for interim and annual periods beginning after December 31, 2021 are not expected to have a material impact on the Company's financial position, results of operations or cash flows.

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 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 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 gains and losses. Other comprehensive income (loss), net includes unrealized losses or gains on short-term investments as well as foreign currency translation losses or gains.

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.

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.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets primarily represent amounts related to director and officer insurance, preclinical research and clinical trial agreements, equity issuance costs and an estimated tax refund for the year ended December 31, 2021 from the Australian Tax Office for eligible research and development expenditures.

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 our right to use an underlying asset for the lease term and lease liabilities represent our 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 we are reasonably certain that the renewal option will be exercised or when it is reasonably certain that the termination option will not be exercised. For our 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. Our 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 other key 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 Company 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.

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.

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, 2021	Year Ended December 31, 2020
Common stock options	3,947,025	2,463,317
Common stock warrants	1,366,141	80,428
Total	5,313,166	2,543,745

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, agency 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):

	December 31, 2021	Fair Value Measurements Using: 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	$ 29,121	$ 29,121	$ -	$ -
Certificates of deposit	1,224	1,224	-	-
Total	$ 30,345	$ 30,345	$ -	$ -

	December 31, 2020	Fair Value Measurements Using: 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	$ 56,220	$ 56,220	$ -	$ -
Certificates of deposit	1,961	1,961	-	-
Total	$ 58,181	$ 58,181	$ -	$ -

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, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. At December 31, 2021 and 2020, the carrying amount of the Company's notes payable of $10.2 million and $9.9 million, respectively, approximated their fair value as the terms of the notes are consistent with the market terms of transactions with similar profiles (Level 2 inputs). None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

At December 31, 2021 and 2020, the Company had investments in money market funds of $45.1 million and $17.4 million, respectively, that were measured at fair value using the net asset value per share (or its equivalent) that have not been classified in the fair value hierarchy. The funds invest primarily in U.S. government securities.

The Company did not hold any Level 1, 2 or 3 financial liabilities that are recorded at fair value on a recurring basis as of December 31, 2021 or 2020.

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, 2021					
U.S. treasury securities	1 or less	$ 17,122	$ -	$ (7)	$ 17,115
U.S. treasury securities	>1 and <5	12,049	-	$ (43)	$ 12,006
Certificates of deposit	1 or less	1,226	-	(2)	1,224
Total		$ 30,397	$ -	$ (52)	$ 30,345
December 31, 2020					
U.S. treasury securities	1 or less	$ 56,218	$ 6	$ (4)	$ 56,220
Certificates of deposit	1 or less	1,955	6	-	1,961
Total		$ 58,173	$ 12	$ (4)	$ 58,181

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. For the years ended December 31, 2021 and 2020, there were net gross realized gains on short-term investments totaling $0 and $13,000, respectively. 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, 2021	December 31, 2020
Furniture & fixtures	$ 60	$ 60
Machinery & lab equipment	282	211
Computer equipment	42	42
Less accumulated depreciation and amortization	(147)	(74)
Property and equipment, net	$ 237	$ 239

Depreciation expense related to property and equipment was approximately $72,000 and $45,000 for the years ended December 31, 2021 and 2020, respectively. No material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2021 or 2020.

6. Leases

The Company's leases relate primarily to office facilities that expire on various dates from 2023 through 2027. The terms of the Company's non-cancelable operating lease arrangements typically contain fixed lease payment which increases 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 $0.3 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively.

Subsequent to the adoption of ASC 842, the Company records its ROU 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, 2021, is as follows (in thousands, except lease term and discount rate):

	December 31, 2021
Balance sheet information	
ROU assets	$ 1,645
Lease liabilities, current	$ 376
Lease liabilities, non-current	1,235
Total lease liabilities	$ 1,611
Other information	
Weighted average remaining lease term	3.78 years
Weighted average discount rate	8.25%
Supplemental cash flow information	
Operating cash flows from operating leases	$ 220
ROU assets obtained in exchange for lease obligations	$ 1,759

Maturities of lease liabilities as of December 31, 2021 were as follows (in thousands):

Year ending December 31,	
2022	$ 510
2023	494
2024	492
2025	192
2026	169
Thereafter	28
Total undiscounted lease payments	1,885
Less: imputed interest	(274)
Total lease liabilities	$ 1,611

As of December 31, 2021, the Company does not have any leases that have not yet commenced that create significant rights and obligations.

Lease commitments in accordance with prior guidance

Future minimum lease payments under non-cancelable operating leases, including short-term leases as of December 31, 2021 were as follows (in thousands):

Years Ending December 31,	
2022	$ 510
2023	494
2024	492
2025	192
2026	169
Thereafter	28
Total minimum lease payments	$ 1,885

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Accrued payroll and other employee benefits	$ 2,511	$ 1,870
Clinical studies	2,627	493
Other accruals	245	307
Preclinical studies	432	72
Accrued interest	71	71
Total accrued expenses	$ 5,886	$ 2,813

8. Collaboration and License Agreement

In May 2017, the Company entered into a collaboration and license agreement (which was amended in September 2018, April 2019 and December 2019), 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 Company Territory). However, unless the Company achieves certain regulatory and development milestones within a specific time period, the licensed rights, other than development rights, are limited to the fields of orphan indications and the treatment of conditions related to asthma and lupus. 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 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 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 the Company royalties at comparable percentages for sales of itolizumab (EQ001) outside of the Company Territory if the approvals in such geographies included or referenced the Company's data including data from certain of the Company's clinical trials, subject to adjustments in certain circumstances. 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, 2021, the Company has not made or received payments in connection with the milestones or royalties within the agreement.

9. 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) whereby the Company could borrow up to $20.0 million in a series of term loans. Upon entering into the Loan Agreement, the Company borrowed $10.0 million from the Lenders (the Term Loan).

As of December 31, 2020, the Company was no longer eligible to receive the additional funding up to $10.0 million under the Loan Agreement.

The Term Loan matures on June 1, 2024 (the Maturity Date) and requires interest-only payments through June 30, 2021, followed by 36 equal monthly payments of principal and interest. The Term Loan bears interest 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 precedes the month in which the interest will accrue, plus (b) 3.00%.

On December 18, 2020, the Company entered into the First Amendment to the Loan Agreement (the First Amendment) with the Lenders whereby if the Company achieved positive topline data in either the Company's (a) Phase 1b aGVHD trial of itolizumab (EQ001) or (b) Phase 1b asthma trial of itolizumab (EQ001), supporting a formal decision to advance into Phase 2 development, and as confirmed by the Board of Directors (the Board) of the Company on or prior to June 30, 2021, the interest-only payments would be automatically extended through December 31, 2021.

On April 23, 2021, the Company entered into the Second Amendment to the Loan Agreement (the Second Amendment) which added two new milestones: (i) 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 (ii) the Company initiating a pivotal Phase 3 aGVHD trial (the Interest-Only Extension II Milestone). If the Company achieves the Interest-Only Extension Milestone on or prior to June 30, 2021, then interest-only payments will be automatically extended through June 30, 2022. If the Company achieves the Interest-Only Extension II Milestone on or prior to June 30, 2022, then interest-only payments will be automatically extended through September 30, 2022. The Second Amendment also amended the final payment percentage from 4.5% to 5.0%.

In May 2021, the Company achieved the Interest-Only Extension Milestone. Due to the achievement of the Interest-Only Extension Milestone, the interest-only payments were extended through June 30, 2022, followed by 24 equal monthly principal payments and interest. In March 2022, the Company obtained confirmation from Lenders that the Interest-Only Extension II milestone had been achieved, which further extends the interest-only payments through September 30, 2022.

Under authoritative guidance, the Second Amendment does not meet the criteria to be accounted for as a troubled debt restructuring. In addition, the Company performed a quantitative analysis and determined that the terms of the new debt and original debt instrument are not substantially different. Accordingly, the Second Amendment is accounted for as a debt modification. A new effective interest rate that equates the revised cash flows to the carrying amount of the original debt was computed and applied prospectively. The new effective interest rate is 10.58%.

In February 2022, the Company entered into the Third Amendment to the Loan Agreement (the Third Amendment) which added Bioniz Therapeutics, Inc. as a secured party to the loan.

The Company will be 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, or (iii) the prepayment of the Term Loan (the Final Payment). The Company may prepay all, but not less than all, of the Term Loan upon 30 days' advance written notice to the lender, provided that the Company will be 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 is the closing price of the Company's common stock reported on the Nasdaq Global Market 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.

The Company recorded the Warrants as a debt discount, which is classified as a contra-liability against long-term notes payable on the consolidated balance sheet and is amortizing the balance over the life of the underlying debt. The offset to the contra-liability is recorded in additional paid in capital in the Company's consolidated balance sheet as the Warrants were determined to be equity classified. The Company determined the fair value of the Warrants at the date of issuance was $0.3 million using the Black-Scholes option pricing model based on significant unobservable inputs (Level 3) with an expected term of 10 years, volatility of 92.78%, risk free rate of 1.68% and expected dividend of 0%.

The costs incurred to issue the Term Loan of $0.1 million were deferred and are included in the discount to the carrying value of the Term Loan in the accompanying consolidated balance sheet. The deferred costs and the Final Payment fee are amortized to interest expense over the expected term of the Term Loan using the effective interest method with an effective interest rate of 10.97%.

The aggregate carrying amounts of the Term Loan is comprised of the following (in thousands):

	December 31, 2021	December 31, 2020
Principal	$ 10,000	$ 10,000
Add: accreted liability for final payment fee	310	176
Less: unamortized discount	(132)	(235)
Total	$ 10,178	$ 9,941

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreement, the breach of certain of its other covenants under the Loan Agreement, or the occurrence of a material adverse change, cross defaults to other indebtedness or material agreements, judgment defaults and defaults related to failure to maintain governmental approvals failure of which to maintain could result in a material adverse effect, the Company's lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, to exercise secured party remedies, to receive the Final Payment and, if the payment of principal and interest is due prior to the Maturity Date, to receive the applicable Prepayment Fee. At December 31, 2021, the Company was in compliance with the covenants contained in the Loan Agreement.

Future maturities of the Term Loan, including the Final Payment fee, as of December 31, 2021 were as follows (in thousands):

Year ending December 31, 2022	$	1,428
Year ending December 31, 2023		5,714
Year ending December 31, 2024		3,358
		10,500
Unaccreted balance for Final Payment fee on Term Loans		(190)
Unamortized discounts		(132)
		10,178
Less current portion		(1,428)
Noncurrent portion	$	8,750

10. Stockholders' Equity

As of December 31, 2021, 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 29,455,668 and 24,753,102 shares of common stock outstanding as of December 31, 2021 and 2020, respectively.

Registered Direct Offering and related warrants

On February 3, 2021, the Company entered into a securities purchase agreement (the Securities Purchase Agreement) with two institutional investors (the Purchasers), relating to the issuance and sale (the Offering) of an aggregate of 4,285,710 shares of common stock and warrants to purchase 1,285,713 shares of common stock (the Warrants) for aggregate gross proceeds to the Company from this Offering of approximately $30.0 million, excluding any proceeds the Company may receive upon exercise of the Warrants. No underwriter or placement agent participated in the Offering. The proceeds, net of related issuance costs, were $29.9 million.

The Warrants are exercisable immediately upon issuance at an initial exercise price of $14.00 per share and are exercisable on a cashless basis. The Warrants expire on the earlier of (i) the fifth anniversary of issuance or (ii) the 15th calendar date following the date on which the Company closes upon an equity financing that results in not less than $25 million of gross proceeds to the Company at a price per share of common stock equal to or greater than $25.00, at which time, all remaining Warrants will automatically be exercised on a cashless basis. The exercise price and the number of shares of common stock purchasable upon the exercise of the Warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, reclassifications and combinations of the Company's common stock. All of the warrants are recorded within equity in accordance with authoritative accounting guidance.

Pursuant to the terms of the Securities Purchase Agreement, the Company appointed Dr. Yu (Katherine) Xu, Ph. D. to the Board as a nominee of the Purchasers.

Follow-On Public Offering

In August 2020, the Company completed an underwritten public offering of 5,461,169 shares of common stock at $7.00 per share, which included 461,169 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. The Company received gross proceeds from this offering totaling $38.2 million. The proceeds, net of underwriting discounts and related issuance costs, were $35.7 million.

At-the-Market Offering Program

In November 2019, the Company entered into an Open Market Sales Agreement[SM] with Jefferies LLC (Jefferies) under which the Company could offer and sell shares of its common stock from time to time, through an "at-the-market" (ATM), equity offering program under which Jefferies acted as sales agent (2019 ATM Facility). The Company set certain parameters for the sale of shares, which included but were not limited to the number of shares to be issued, the time period during which sales are requested to be made, and any minimum price below which sales may not be made. Jefferies was entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses.

The maximum aggregate offering price of common stock that could be sold under the 2019 ATM Facility was $8.45 million. During the year ended December 31, 2020, the Company sold an aggregate 925,489 shares of its common stock and received gross proceeds of $8.4 million under the 2019 ATM Facility. The Company paid commissions on the gross proceeds in the aggregate amount of approximately $0.3 million, during the year ended December 31, 2020, resulting in net proceeds of $8.1 million. As of December 31, 2020, the 2019 ATM Facility was fully utilized.

On July 14, 2020, the Company entered into a new ATM equity offering program (2020 ATM Facility) with Jefferies under which the Company may offer and sell shares of the Company's common stock having an aggregate price of up to $150 million, from time to time, through Jefferies acting as our sales agent. As of December 31, 2021, the Company had sold an aggregate of 788,685 shares of common stock under the 2020 ATM Facility and received gross proceeds of $10.4 million. The Company paid cash commissions on the gross proceeds, plus reimbursement expenses to Jefferies and other issuance costs in the aggregate amount of approximately $0.4 million, resulting in net proceeds of $10.0 million. Since December 31, 2021 and through the date of the filing of this Annual Report on Form 10-K, there have been no additional sales of the Company's stock under the 2020 ATM Facility.

Purchase Agreement

In March 2020, the Company entered into a purchase agreement (Purchase Agreement), with Lincoln Park Capital Fund, LLC (Lincoln Park), which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $15.0 million of shares of its common stock from time to time over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company issued 65,374 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of the Company's common stock on the effective date of the Purchase Agreement resulting in a fair market value of approximately $0.2 million. The fair market value of the commitment shares as well as other issuance costs associated with the Purchase Agreement totaled $0.4 million. These issuance costs are classified as prepaid expenses and other current assets in the accompanying consolidated balance sheet. As shares of common stock are sold to Lincoln Park in accordance with the Purchase Agreement, the issuance costs, including the fair value of the commitment shares, will be reclassified to additional paid-in capital on the Company's consolidated balance sheet. There have been no sales of the Company's common stock under this Purchase Agreement as of December 31, 2021 and through the date of the filing of this Annual Report on Form 10-K.

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, 2021, the 2018 Plan had a maximum of 467,024 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, 2021:

	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, 2020	2,463,317	$ 3.71	7.98	$ 4,726
Granted	1,939,080	$ 5.42		
Exercised	(326,454)	$ 2.73		
Forfeitures and cancellations	(128,918)	$ 5.17		
Balances as of December 31, 2021	3,947,025	$ 4.58	8.38	$ 1,501
Options exercisable as of December 31, 2021	1,342,186	$ 3.94	7.68	$ 941

(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, 2021 of $3.77 and the price of the underlying options.

The aggregate intrinsic value of stock options exercised was $0.4 million and $9,000 for the years ended December 31, 2021 and 2020, respectively. Cash received from stock options exercised was $0.9 million and $7,000 for the years ended December 31, 2021 and 2020, respectively.

The fair value of stock options that vested in the years ended December 31, 2021 and 2020 was $3.0 million and $4.1 million, respectively. The weighted-average grant-date fair value of options granted was $3.94 and $3.11 for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, unrecognized compensation expense related to unvested stock options was $9.2 million and is expected to be recognized over a weighted-average period of 2.6 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, 2021, the Company had issued 169,166 shares of common stock under the ESPP, 90,402 of which were issued during the year ended December 31, 2021. The Company had 769,658 shares available for future issuance under the ESPP as of December 31, 2021.

Liability for Early Exercise of Restricted Stock Options

All stock option grants under the 2017 Plan provide for exercise of the stock option prior to vesting. Shares of common stock issued upon exercise of unvested options are subject to repurchase by the Company at the respective original exercise price until vested. Consideration received for the exercise of unvested stock options is recorded as a liability and reclassified into equity as the related award vests.

As of December 31, 2021 and 2020, 43,135 and 153,690 unvested shares issued under early exercise provisions were subject to repurchase by the Company, respectively. The balance sheet reflects an unvested stock liability of $53,000 and $125,000

as of December 31, 2021 and 2020, respectively. As of December 31, 2021, all of the unvested stock liability is considered short-term and is classified as accrued expenses on the accompanying consolidated balance sheet. As of December 31, 2020, the short and long-term portion of the unvested stock liability was $72,000 and $53,000, respectively. The short-term unvested stock liability is classified as accrued expenses and the long-term unvested stock liability is classified as other non-current liabilities on the accompanying consolidated balance sheet.

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, 2021	Year Ended December 31, 2020
Research and development	$ 1,976	$ 1,773
General and administrative	2,434	2,044
Total	$ 4,410	$ 3,817

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, 2021	Year Ended December 31, 2020
Risk-free interest rate	0.68%	0.65%
Expected volatility	88.55%	89.56%
Expected term (in years)	6.01	5.77
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 not 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, 2021 and 2020:

	December 31, 2021	December 31, 2020
Stock options issued and outstanding	3,947,025	2,463,317
Warrants for common stock	1,366,141	80,428
Awards available under the 2018 Equity Incentive Plan	467,024	1,039,531
Employee stock purchase plan	769,658	612,529
Total	6,549,848	4,195,805

11. Commitments and Contingencies

Leases and Other Commitments

The Company leases certain office space in La Jolla and South San Francisco, California under non-cancelable operating leases. The leases for spaces in La Jolla and South San Francisco expire under various dates up until February 2027. Rent expense was $0.3 million for both the years ended December 31, 2021 and 2020.

In November 2021, the Company leased 4,727 square feet of office space in San Diego, California under a non-cancelable operating lease with a term of three years which commenced in February 2022. The total minimum lease payment over the life of the lease is $0.9 million.

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, 2021, there was no litigation against the Company.

12. Income Taxes

The components of loss before income tax provision (benefit) for the years ended December 31, 2021 and 2020 consisted of the following (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020
U.S.	(37,705)	(29,420)
Foreign	(1,347)	(393)
	$ (39,052)	$ (29,813)

The Company has not recorded a current or deferred tax expense or benefit for the years ended December 31, 2021 and 2020.

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, 2021 and 2020 (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020
Income taxes at statutory rates	$ (8,201)	$ (6,261)
State income tax, net of federal benefit	-	-
Stock-based compensation	451	97
Permanent items	31	15
Federal research and orphan drug credits	(1,713)	(445)
Foreign rate differential	72	367
Change in federal valuation allowance	9,360	6,227
	$ -	$ -

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, 2021 and 2020 are as follows (in thousands):

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating loss carryforward	$ 19,344	$ 12,338
Credits	3,940	1,940
Intangibles	108	118
Equity compensation	1,134	888
Other	1,076	286
Total deferred tax assets	25,602	15,570
Valuation allowance	(25,215)	(15,564)
Total deferred tax assets, net of allowance	$ 387	$ 6
Deferred tax liabilities:		
Operating lease right-of-use asset	(346)	-
Other	(41)	(6)
Total deferred tax liabilities	$ (387)	$ (6)
Net deferred taxes	$ -	$ -

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 $25.2 million as of December 31, 2021 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 $9.7 million during the year ended December 31, 2021.

At December 31, 2021, the Company had federal and California tax loss carry-forwards of approximately $86.4 million and $56.0 million, respectively. The federal net operating loss carryover includes $85.5 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 in taxable years beginning after December 31, 2020 is limited to 80% of taxable income. The federal net operating losses generated prior to 2018 as well as the state net operating loss carry-forwards, begin to expire in 2037 unless previously utilized. The Company has $2.4 million of Australian net operating loss carryforwards as of December 31, 2021 that are carried forward indefinitely.

At December 31, 2021, the Company had federal and state tax credit carry-forwards of approximately $3.2 million and $0.9 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 2037, if unused, and the state credits carry forward indefinitely.

Pursuant to the Internal Revenue Code of 1986, as amended (IRC), specifically Section 382 and 383, the Company's ability to use net operating loss and research and development tax credit carry forwards (tax attribute carry forwards) 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 has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining tax attribute carry-forwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, our deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382.

The following table summarizes the reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020
Unrecognized tax benefits – beginning	$ 2,667	$ 360
Gross increases – tax positions in prior period	2,266	1,988
Gross decreases – tax positions in prior period	-	-
Gross increase – current-period tax positions	554	319
Gross decrease – current-period tax positions	-	-
Settlements	-	-
Lapse of statute of limitations	-	-
Unrecognized tax benefits – ending	$ 5,487	$ 2,667

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, 2021 and has not recognized interest and/or penalties in the consolidated statement of operations for the year ended December 31, 2021.

All tax years for both federal and state purposes remain open and subject to examination by tax jurisdictions.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions are the extension of the carryback period of certain losses to five years, and the suspension of the 80 percent limitation imposed by the Tax Cuts and Jobs Act of 2017 (TCJA) on utilization of net operating losses generated in 2018, 2019 and 2020 to offset taxable income generated in tax years prior to 2021. The CARES Act also increased the ability to deduct interest expense from 30 percent, as imposed by the TCJA, to 50 percent of modified taxable income. The CARES Act also provides a credit against employee wages, the opportunity to defer payment of a portion of federal payroll taxes to December 2021 and December 2022, and enhanced small business loans to assist businesses impacted by the pandemic. The Company's tax provision and financial position was not materially impacted by the CARES Act.

On December 27, 2020, the United States enacted the Consolidated Appropriations Act, which extended and modified many of the tax related provisions of the CARES Act. The Company does not anticipate a material impact of the Consolidated Appropriations Act on its tax provision or financial position.

The 2017 tax reform act amended the Internal Revenue Code ("Code"), effective for amounts paid or incurred in tax years beginning after December 31, 2021, to eliminate the immediate expensing of research and experimental expenditures ("R&E") 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).

13. 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 not make any contributions for the years ended December 31, 2021 or 2020.

14. Subsequent Events

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 Therapeutics, Inc., a Delaware corporation ("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 as set forth in the Merger Agreement. The closing issuance of Merger Shares may be adjusted after the closing, pursuant to procedures set forth in the Merger Agreement, in connection with the finalization of transaction expenses, debt, net exercise taxes and working capital amounts at closing.

Bioniz is a privately held clinical-stage biotechnology company. Bioniz developed its novel structured-domain peptides, including BNZ-1 and BNZ-2, entirely in-house from its proprietary product discovery platform. The Bioniz lead product candidates are multi-specific inhibitors of key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immuno-inflammatory indications. Upon completion of the acquisition, the Bioniz subsidiary was made a borrower to the Term Loans under the Third Amendment to our Loan Agreement.

Exhibit 10.23

FIRST AMENDMENT TO
LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT to Loan and Security Agreement (this "**Amendment**") is entered into as of December 18, 2020 (the "**Amendment Date**"), by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 to the Loan Agreement (as defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender and SILICON VALLEY BANK, a California corporation with an office located at 3003 Tasman Drive, Santa Clara, California 95054 ("**Bank**" or "**SVB**") (each a "**Lender**" and collectively, the "**Lenders**"), and EQUILLIUM, INC., a Delaware corporation with offices located at 2223 Avenida de la Playa, Suite 108, La Jolla, California 92037 ("**Borrower**").

RECITALS

A. Collateral Agent, Borrower and Lenders have entered into that certain Loan and Security Agreement, dated as of September 30, 2019 (as amended, supplemented or otherwise modified from time to time, the "**Loan Agreement**") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof.

B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Collateral Agent and Lenders (i) modify the amortization schedule and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. Collateral Agent and Lenders have agreed to modify and to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 10 (Notices). Effective as of December 14, 2020, Collateral Agent's Notice information in Section 10 of the Loan Agreement hereby is amended and restated as follows:

"OXFORD FINANCE LLC
115 South Union Street, Suite 300
Alexandria, VA 22314
Attention: Legal Department

Fax: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com"

2.2 **Section 13.1 (Definitions)**. The following term and its definition in Section 13.1 of the Loan Agreement hereby is amended and restated as follows:

"**Amortization Date**" is, July 1, 2021; provided, however, if a Borrower achieves the Term B Milestone on or prior to June 30, 2021, then the Amortization Date with respect to all Term Loans shall automatically be extended to January 1, 2022.

3. **Limitation of Amendment**.

3.1 The amendments set forth in **Section 2**, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. **Representations and Warranties**. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any

order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower;

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights; and

4.8 That certain Intellectual Property License Agreement by and between Borrower and Equillium Australia and effective as of January 30, 2019 does not violate the restrictions placed on Equillium Australia under Section 7.12 of the Loan Agreement.

5. Release by Borrower.

5.1 FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Collateral Agent and each Lender and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Amendment solely to the extent such claims arise out of or are in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing (collectively "Released Claims").

5.2 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected in respect of the Released Claims; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Bank with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and the Lenders to enter into this Amendment, and that Collateral Agent and the Lenders would not have done so but for Collateral Agent's and the Lenders' expectation that such release is valid and enforceable in all events.

5.4 Borrower hereby represents and warrants to Collateral Agent and the Lenders, and Collateral Agent and the Lenders are relying thereon, as follows:

(a) Except as expressly stated in this Amendment, neither Collateral Agent, the Lenders nor any agent, employee or representative of any of them has made any statement or representation to Borrower regarding any fact relied upon by Borrower in entering into this Amendment.

(b) Borrower has made such investigation of the facts pertaining to this Amendment and all of the matters appertaining thereto, as it deems necessary.

(c) The terms of this Amendment are contractual and not a mere recital.

(d) This Amendment has been carefully read by Borrower, the contents hereof are known and understood by Borrower, and this Amendment is signed freely, and without duress, by Borrower.

(e) Borrower is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Borrower shall indemnify Collateral Agent and the Lenders, defend and hold each harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

7. Effectiveness. This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, and (ii) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to the Loan Agreement to be executed as of the date first set forth above.

BORROWER:

EQUILLIUM, INC.

By: /s/ Jason Keyes
Name: Jason Keyes
Title: Chief Financial Officer

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC.

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

LENDER:

SILICON VALLEY BANK

By: /s/ Kevin Fleishman
Name: Kevin Fleischman
Title: Director

EQUILLIUM, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY
(amended and restated, effective as of March 1, 2022)

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Equillium, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $42,000
   b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $20,000
2. Annual Committee Chair Service Retainer:
   a. Chairman of the Audit Committee: $20,000
   b. Chairman of the Compensation Committee: $15,000
   c. Chairman of the Nominating and Corporate Governance Committee: $10,000
3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
   a. Member of the Audit Committee: $10,000
   b. Member of the Compensation Committee: $7,500
   c. Member of the Nominating and Corporate Governance Committee: $5,000

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2018 Equity Incentive Plan (the "***Plan***"). All stock options granted under this policy will be nonstatutory stock options, with an exercise

price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company (the "***Common Stock***") on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for death, disability or cause, the post-termination exercise period will be 12 months from the date of termination).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be granted a stock option to purchase 40,000 shares of Common Stock (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each annual stockholder meeting of the Company, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholder meeting will be granted a stock option to purchase 20,000 shares of Common Stock (the "***Annual Grant***"). The shares subject to the Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will in any case be fully vested on the date of Company's next annual stockholder meeting, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

3. Revisions: To the extent that the price of the Company's Common Stock shall change (increase or decrease) by twenty-five percent (25%) or more since the later of the date of (a) adoption of this Non-Employee Director Compensation Policy or (b) the last Initial Grant, then the number of shares subject to an Initial Grant may be increased or decreased, as the case may be, to reflect the proportional change in the price of the Company's Common Stock, as determined by the Compensation Committee prior to such Initial Grant.

EXHIBIT 10.28

CONSENT AND THIRD AMENDMENT TO
LOAN AND SECURITY AGREEMENT

THIS CONSENT AND THIRD AMENDMENT to Loan and Security Agreement (this "**Amendment**") is entered into as of February 14, 2022, by and between OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, VA 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 to the Loan Agreement (as defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender and SILICON VALLEY BANK, a California corporation with an office located at 3003 Tasman Drive, Santa Clara, California 95054 ("**Bank**" or "**SVB**") (each a "**Lender**" and collectively, the "**Lenders**") including Oxford in its capacity as a Lender, EQUILLIUM, INC., a Delaware corporation with offices located at 2223 Avenida de la Playa, Suite 105, La Jolla, California 92037 ("**Existing Borrower**"), and BIONIZ THERAPEUTICS, INC., a Delaware corporation with offices located at 5 Mason, Ste 275, Irvine, CA 92618 ("**Bioniz**" or "**New Borrower**" and together with Existing Borrower, individually and collectively, jointly and severally, "**Borrower**").

RECITALS

A. Collateral Agent, Lenders and Existing Borrower have entered into that certain Loan and Security Agreement dated as of September 30, 2019 (as amended, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of December 18, 2020 and that certain Second Amendment to Loan and Security Agreement dated as of April 23, 2021, collectively, the "**Loan Agreement**") pursuant to which Lenders have provided to Existing Borrower certain loans in accordance with the terms and conditions thereof.

B. Lenders have extended credit to Existing Borrower for the purposes permitted in the Loan Agreement.

C. Existing Borrower has formed wholly owned subsidiary Project JetFuel Merger Sub, Inc., a Delaware corporation ("**Merger Sub**"), for the purpose of acquiring New Borrower via a merger with Merger Sub whereby Merger Sub will be merged with and into New Borrower resulting in New Borrower remaining as a wholly owned subsidiary of Existing Borrower, all pursuant to the terms of that certain Agreement and Plan of Merger (in the form attached hereto as Exhibit A, the "**Merger Agreement**") dated as of February 14, 2022, by and among Existing Borrower, Merger Sub, New Borrower, and Kevin Green, a resident of the State of California, solely in his capacity as stockholder representative.

D. Pursuant to the Loan Agreement the Existing Borrower is required to obtain the prior consent of the Lenders and the Collateral Agent prior to consummating the Merger (as defined in the Merger Agreement as in effect on the date hereof). Existing Borrower has requested that Collateral Agent and Lenders (i) consent to the Merger, (ii) add New Borrower as a Borrower under the Loan Agreement and (iii) make certain other revisions to the Loan Agreement as more fully set forth herein.

E. Collateral Agent and Lenders have agreed to provide such consent and to modify and amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Consent.

2.1 Subject to the terms and conditions hereof, including Section 2.2 hereof, the Collateral Agent and the Lenders hereby consent to Existing Borrower's execution, delivery and performance of the Merger Agreement and consummating the Merger and other transactions contemplated thereby; provided, however, any amendment to the Merger Agreement, including any exhibit or schedule thereto, that would either (a) adversely affect the Lenders or (b) materially and adversely affect Existing Borrower, shall be subject to the prior written approval of the Collateral Agent and the Lenders. Except for the consent set forth in this Section 2.1, the Collateral Agent and the Lenders have not consented to, and are not consenting to, any other transaction or action or inaction in violation of the Loan Agreement or any other Loan Document, whether in connection with the Merger or otherwise. The consent set forth in this Section 2.1 is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document including, without limitation, a waiver of any default or Event of Default under the Loan Agreement resulting from Existing Borrower's failure to consummate the Merger or the breach or fulfilment of any of Existing Borrower's obligations under the Merger Agreement, or (b) otherwise prejudice any right or remedy which Lenders may now have or may have in the future under or in connection with any Loan Document.

2.2 The consent of the Collateral Agent and the Lenders to the execution and delivery of the Merger Agreement and consummating the Merger, is subject to Existing Borrower's satisfaction of the following conditions:

(a) immediately prior to the Merger, and after giving effect to the Merger, no Event of Default shall have occurred and be continuing or would result therefrom;

(b) all transactions in connection with the Merger shall be consummated, in all material respects, in accordance with applicable law;

(c) Bioniz shall be in the same line of business as is conducted by Existing Borrower as of the Effective Date (or a line of business reasonably related thereto);

(d) the Merger shall not cause the focus of Existing Borrower's and its Subsidiaries' operations (when taken as a whole) to be located outside of the United States;

(e) upon consummation of the Merger, Bioniz shall become a wholly owned subsidiary of Existing Borrower;

(f) in connection with the Merger, neither Borrower nor any of its Subsidiaries (including for this purpose, Bioniz or any of its Subsidiaries (if any)) shall acquire or be subject to any Indebtedness (other than Indebtedness consisting of milestone or other earnout consideration owed by Borrower in accordance with the Merger Agreement) or Liens that are not otherwise permitted by the Loan Agreement;

(g) Collateral Agent and Lenders shall have received, at least five (5) Business Days (or such shorter period as may be acceptable to Collateral Agent and Lenders) prior to such proposed acquisition, (i) a copy of the Merger Agreement (and any related documents reasonably requested by the Collateral Agent and Lenders), (ii) a general description of the acquired assets or acquired business line or unit or division and the competitive position of such business line or unit or division within the industry, (iii) the sources and uses of funds to finance the proposed acquisition, and (iv) to the extent available, quarterly and annual audited financial statements of the Person whose Shares or assets are being acquired for the twelve (12) month period immediately prior to such proposed acquisition;

(h) the Merger shall only involve assets located in the United States; provided, however, the Merger may also involve (i) tangible assets located outside the United States so long as the value of such tangible assets does not exceed Five Hundred Thousand Dollars ($500,000.00) in the aggregate with respect to any one acquisition and in the aggregate per fiscal year, and (ii) in-licensing of assets from outside the United States for worldwide application;

(i) Collateral Agent and the Lenders shall have received a certificate from a Responsible Officer together with Board approved projections certifying and setting forth in reasonable detail that Existing Borrower has enough cash on hand to pay its projected expenses and all debt service when due for a period of twelve (12) months after the consummation of such transaction (after giving effect to such transaction);

(j) the Merger shall be consensual and shall have been approved by the Bioniz's board of directors;

(k) Existing Borrower shall have delivered to Collateral Agent and Lenders, in form and substance satisfactory to the Collateral Agent and Lenders and sufficiently in advance (and in any case no later than five (5) Business Days prior to such Permitted Acquisition), such other financial information, financial analysis, documentation or other information relating to such Permitted Acquisition and the pro forma certifications required by clause (l) below, in each case, as Collateral Agent and Lenders shall reasonably request; and

(l) on or prior to the date of the Merger, the Collateral Agent and Lenders shall have received, in form and substance reasonably satisfactory to the Collateral Agent and Lenders, a certificate of the chief financial officer of Existing Borrower certifying compliance with the requirements contained in this Section 2.2 and with the other terms of the Loan Documents.

3. Joinder.

3.1 New Borrower. New Borrower hereby is added as a "Borrower" under the Loan Agreement. All references in the Loan Agreement to "Borrower" shall hereafter mean and include the Existing Borrower and New Borrower individually and collectively, jointly and severally; and New Borrower shall hereafter have all rights, duties and obligations of "Borrower" thereunder.

3.2 Joinder to Loan Agreement. New Borrower hereby joins the Loan Agreement and each of the Loan Documents (other than the Warrants) and agrees to comply with and be bound by all of the terms, conditions and covenants of the Loan Agreement and Loan Documents (other than the Warrants), as if it were originally named a "Borrower" therein. Without limiting the generality of the preceding sentence, New Borrower agrees that it will be jointly and severally liable, together with Existing Borrower, for the payment and performance of all obligations and liabilities of Borrower under the Loan Agreement, including, without limitation, the Obligations. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder. Each Borrower hereunder shall be obligated to repay all Credit Extensions made pursuant to the Loan Agreement, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions.

3.3 Subrogation and Similar Rights. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, including, without limitation, the benefit of California Civil Code Section 2815 permitting revocation as to future transactions and the benefit of California Civil Code Sections 1432, 2809, 2810, 2819, 2839, 2845, 2847, 2848, 2849, 2850, and 2899 and 3433, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Amendment, the Loan Agreement, the Loan Documents or any other related documents, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Amendment and the Loan Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Amendment, the Loan Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Amendment, the Loan Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

3.4 **Grant of Security Interest**. New Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. New Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of the Loan Agreement to have priority to Collateral Agent's Lien. New Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of the Loan Agreement, by New Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

3.5 **Representations and Warranties**. New Borrower hereby represents and warrants to Collateral Agent and each Lender that all representations and warranties in the Loan Documents made on the part of Existing Borrower are true and correct in all material respects on the date hereof with respect to Existing Borrower and New Borrower, with the same force and effect as if New Borrower were named as "Borrower" in the Loan Documents in addition to Existing Borrower.

4. Amendment to Loan Agreement.

4.1 **General**. Each reference to the phrase "[n]either Borrower" in the Loan Agreement hereby is replaced with "[n]o Borrower.":

4.2 **Operating Accounts**. Section 6.6(a) of the Loan Agreement hereby is amended and restated as follows:

"(a) Maintain all of Borrower's or any Loan Party's operating accounts with Bank, in accounts which are subject to a Control Agreement in favor of Collateral Agent, and maintain Borrower's or any Loan Party's primary Banking Services with Bank. Notwithstanding the foregoing, Bioniz may maintain a deposit account at Bank of America, so long as no later than March 14, 2022 such account is subject to a Control Agreement in favor of Collateral Agent and beginning on such date and at all times thereafter, such account does not have a balance of greater than Five Hundred Thousand Dollars ($500,000)."

4.3 **Borrower Liability**. New Section 12.13 is hereby added to the Loan Agreement to read as follows:

"**12.13** **Borrower Liability**. Either Borrower may, acting singly, request Credit Extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting Credit Extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all Credit Extensions made hereunder, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, including, without limitation, the benefit of California Civil Code Section 2815 permitting revocation as to future transactions and the benefit of California Civil Code Sections 1432, 2809, 2810, 2819, 2839, 2845, 2847, 2848, 2849, 2850, and 2899 and 3433, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower,

or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured."

5. Limitation of Joinder and Amendment.

5.1 The consent, joinder and amendment set forth in **Sections 2, 3** and **4** are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

5.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

6. Representations and Warranties. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

6.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that are already qualified or modified by materiality in the text thereof), except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date, and (b) no Event of Default has occurred and is continuing;

6.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

6.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on or prior to the date hereof remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

6.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

6.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

6.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and

6.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may

be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

7. Release by Borrower.

7.1 **FOR GOOD AND VALUABLE CONSIDERATION**, Borrower hereby forever relieves, releases, and discharges Collateral Agent and each Lender and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Amendment solely to the extent such claims arise out of or are in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing (collectively "**Released Claims**").

7.2 In furtherance of this release, Borrower expressly acknowledges and waives the provisions of California Civil Code Section 1542 (and any similar provision under the laws of any state), which states:

> "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

7.3 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected in respect of the Released Claims; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Collateral Agent or Lenders with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and the Lenders to enter into this Amendment, and that Collateral Agent and the Lenders would not have done so but for Collateral Agent's and the Lenders' expectation that such release is valid and enforceable in all events.

8. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

9. Effectiveness. This Amendment shall be deemed effective upon delivery to Collateral Agent and Lenders of the following, in form and content acceptable to Collateral Agent and Lenders:

(a) this Amendment duly executed by each party hereto;

(b) the Corporate Borrowing Certificate attached hereto duly executed by New Borrower;

(c) a Perfection Certificate duly executed by New Borrower;

(d) Amended and Restated Secured Promissory Notes duly executed by each Borrower;

(e) good standing certificates for New Borrower certified by the Secretary of State (or equivalent agency) of the State of Delaware and each jurisdiction in which New Borrower is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the date of this Amendment;

(f) a duly filed UCC Financing Statement with the Secretary of State of the State of Delaware, identifying New Borrower as a debtor;

(g) the certificates and information required by Sections 2.2(i), 2.2(k) and 2.2(l) hereof; and

(h) Borrower's payment of all Lenders' Expenses to the extent invoiced through the date of this Amendment.

10. Conditions Subsequent. Borrower agrees to provide each of the following to Collateral Agent and Lenders and Borrower acknowledges and agrees that its failure to deliver any of the following in accordance with the deadline for such item shall be an immediate Event of Default under the Loan Agreement:

(a) no later than thirty (30) days after the date hereof (or such longer period as Collateral Agent shall agree in writing in its discretion), Collateral Agent and Lenders shall have received, in form and substance reasonably satisfactory to Collateral Agent, fully-executed Control Agreements in favor of Collateral Agent for all Collateral Accounts of New Borrower required by Section 6.6 of the Loan Agreement;

(b) no later than thirty (30) days after the date hereof (or such longer period as Collateral Agent shall agree in writing in its discretion), Collateral Agent and Lenders shall have received, in form and substance reasonably satisfactory to Collateral Agent, a fully-executed landlord waiver for New Borrower's leased real property at 5 Mason, Ste 275, Irvine, CA 92618;

(c) no later than thirty (30) days after the date hereof (or such longer period as Collateral Agent shall agree in writing in its discretion), Collateral Agent and Lenders shall have received, in form and substance reasonably satisfactory to Collateral Agent, a fully-executed bailee waiver in favor of Collateral Agent in respect of each third party bailee where New Borrower maintains Collateral having a book value in excess of Five Hundred Thousand Dollars ($500,000.00); and

(d) no later than thirty (30) days after the date hereof (or such longer period as Collateral Agent shall agree in writing in its discretion), Collateral Agent and Lenders shall have received, in form and substance reasonably satisfactory to Collateral Agent, evidence of all insurance required to be maintained pursuant to the Loan Documents and all endorsements in favor of the Collateral Agent required under the Loan Documents have been obtained and are in effect.

[*Balance of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

LENDER:

SILICON VALLEY BANK

By: /s/ Kristine Rohmer
Name: Kristine Rohmer
Title: Director

BORROWER:

EQUILLIUM, INC.

By: /s/ Jason Keyes
Name: Jason Keyes
Title: Chief Financial Officer

BIONIZ THERAPEUTICS, INC.

By: /s/ Jason Keyes
Name: Jason Keyes
Title: Chief Financial Officer

Exhibit A

Merger Agreement

Exhibit 10.29

CONFIDENTIAL SEPARATION AGREEMENT
AND GENERAL RELEASE OF ALL CLAIMS

This Confidential Separation Agreement and General Release of All Claims ("Separation Agreement") is made by and between Equillium, Inc. ("Company") and Dolca Thomas ("Employee"). The Company and Employee may also be referred to in this Separation Agreement as a Party and collectively as "the Parties."

A. WHEREAS, Employee is currently employed by Company as Chief Medical Officer and Executive Vice President of Research and Development pursuant to a letter agreement ("Offer Letter") dated December 13, 2020; and

B. WHEREAS, Employee resigned from her employment with the Company on February 11, 2022, effective February 25, 2022.

C. WHEREAS, the Parties desire to settle all claims and issues that have, or could have been raised, in relation to Employee's employment with Company and arising out of or in any way related to the acts, transactions or occurrences between Employee and Company to date, including, but not limited to, Employee's employment with Company or the termination of that employment, on the terms set forth below.

NOW THEREFORE, in consideration of the promises and mutual agreements hereinafter set forth, it is agreed by and between the undersigned as follows:

1. Separation Date. Employee's employment with Company will conclude on February 25, 2022 ("Separation Date"). Employee will receive her final paycheck on the Separation Date. Employee will not be expected in the interim period between the date of execution of this Separation Agreement and the Separation Date to perform any functions or duties other than of a transitory nature.

2. Separation Payments. Company agrees to provide Employee with the following payments ("Separation Payments") in the amount of $169,727.44, which shall be paid on or before the Separation Date regardless of whether this Agreement becomes effective as delineated in Section 14.2.

2.1 Payment of salary earned but unpaid from the last pay period through the Separation Date, totaling approximately $18,908.85;

2.2 Payment of a discretionary bonus for calendar year 2021 in the amount of $146,251.28;

2.3 Refund of ESPP balance as of today in the amount of $4,567.31.

Employee /s/ DT
Company /s/ BS

3. Separation Benefits. In addition to the Separation Payments set forth above, Company agrees to provide Employee with the following payments and benefits ("Separation Benefits") to which it contends Employee is not otherwise entitled. Employee acknowledges and agrees that these Separation Benefits constitute adequate legal consideration for the promises and representations made by Employee in this Separation Agreement and for the general release given by Employee. All Separation Benefits described in this Section 3 are contingent upon Employee's execution of this Separation Agreement and Employee's re-execution of the general release contained herein, contained in the attached Addendum to Separation Agreement, on the Effective Date.

3.1 Company agrees to provide Employee with separation payments in the gross amount of **$**276,573.39 (excluding COBRA benefits), less all required federal and state income and employment taxes and withholdings. The Separation Benefits will be paid within two (2) business days of the Effective Date as set forth in Paragraph 14.2 below.

3.1.1 Payment of a prorated 2022 discretionary bonus (assuming 100% achievement of goals) through February 25, 2022 in the amount of $30,758.39;

3.1.2 A severance payment in the amount of $245,815.00, which represents six (6) months of Employee's base salary;

3.1.3 Continuation of Group Health Benefits. Company agrees to pay the premiums required to continue Employee's and Employee's dependents' group health care coverage through **August 30, 2022**, under the applicable provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), provided that Employee timely elects to continue and remains eligible for these benefits under COBRA and does not become eligible for health coverage through another employer during this period; and

4.Disclosures Regarding Employee Separation. Company agrees that in response to any inquiry to Company's Human Resources Department, Company will provide a neutral reference limited to Employee's dates of employment and position held.

5.General Releases.

1.1Employee unconditionally, irrevocably and absolutely releases and discharges Company, and any parent and subsidiary corporations, divisions and affiliated corporations, partnerships or other affiliated entities of Company, including but not limited to Equillium AUS Pty Ltd**.** and with respect to each entity, all of its past and present employees, officers, directors, shareholders, agents, successors and assigns (collectively, "Employee Released Parties") from all claims related in any way to the transactions or occurrences between them to date, to the fullest extent permitted by law, including but not limited to Employee's employment with Company, the termination of Employee's employment, and all other losses, liabilities, claims, charges, demands and causes of action, known or unknown, suspected or unsuspected, arising directly or indirectly out of or in any way connected with Employee's employment with Company. This release is intended to have the broadest possible application and includes, but is not limited to, any local, state, or federal tort, contract, whistleblower, discrimination, harassment, retaliation, common law, constitutional or other statutory claims, including but not limited to alleged violations of the California Labor Code, California Industrial Welfare Commission wage orders, California Business and Professions Code, California Fair Employment and Housing Act, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, Section 1981 of the Civil Rights Act of 1866, the Equal Pay Act, the Genetic Information Nondiscrimination Act, and the Age Discrimination in Employment Act of 1967, as amended, any claims for wrongful termination and/or violation of public policy, any claims for breach of fiduciary duty, any claims for violation of Company and/or the Released Parties' bylaws, policies, procedures or other governing documents, and any and all claims for attorneys' fees, costs and expenses. This release shall not affect or modify Employee's rights to indemnification from the Company, if any, that may arise under her Offer Letter or statutory or common law as to any acts or omissions of Employee, during her employment and within the course and scope of that employment.

2.1Employee acknowledges that Employee may discover facts or law different from, or in addition to, the facts or law that Employee knows or believes to be true with respect to the claims released in this Separation Agreement and agrees, nonetheless, that this Separation Agreement and the release contained in it shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them.

Employee __/s/ DT
Company __/s/ BS

2.2Employee declares and represents that Employee intends this Separation Agreement to be complete and not subject to any claim of mistake, and that the release herein expresses a full and complete release and Employee intends the release herein to be final and complete. Employee executes this release with the full knowledge that this release covers all possible claims against the Employee Released Parties, to the fullest extent permitted by law. Employee understands and agrees that a condition of Employee's receipt of the Separation Benefits is that Employee shall re-execute these general release provisions (5.1 through 5.4) on the Effective Date.

2.3This General Release is not intended to bar any claims that, by law, may not be waived, such as claims for workers' compensation benefits, unemployment insurance benefits, statutory indemnity, and any challenge to the validity of Employee's release of claims under the Age Discrimination in Employment Act of 1967, as amended, if applicable. This General Release does not prevent Employee from contacting, providing information to, or filing a charge with any federal, state or local government agency or commission, including but not limited to the Equal Employment Opportunity Commission ("EEOC"), the Securities and Exchange Commission ("SEC"), or the National Labor Relations Board ("NLRB"). Employee is prevented, however, to the maximum extent permitted by law, from obtaining any monetary or other personal relief for any of the claims Employee has released in this Paragraph 2 and its subparts with regard to any charge or claim Employee may file or which may be filed or otherwise brought on Employee's behalf. Nothing in this Agreement is intended to or shall be interpreted to restrict or otherwise interfere with: (i) Employee's obligation to testify truthfully in any forum; or (ii) Employee's right and/or obligation to contact, cooperate with, provide information to, or participate in any investigation conducted by, any government agency or commission (including but not limited to the EEOC, SEC or NLRB).

2.4The Company, including but not limited to Equillium AUS Pty Ltd., and with respect to each entity, all of its past and present employees, officers, directors, shareholders, agents, successors and assigns (collectively, "Company Released Parties"), unconditionally, irrevocably and absolutely release and discharge Employee from all claims related in any way to the transactions or occurrences between them to date, to the fullest extent permitted by law, including but not limited to Employee's employment with Company, the termination of Employee's employment, and all other losses, liabilities, claims, charges, demands and causes of action, known or unknown, suspected or unsuspected, arising directly or indirectly out of or in any way connected with Employee's employment with Company. This release is intended to have the broadest possible application and includes, but is not limited to, any local, state, or federal tort, contract, common law, constitutional or other statutory claims, including but not limited to alleged violations of the California Business and Professions Code, any claims for breach of contract and/or violation of public policy, any claims for breach of fiduciary duty, any claims for violation of

Company bylaws, policies, procedures or other governing documents, and any and all claims for attorneys' fees, costs and expenses.

2.5The Company acknowledges that it may discover facts or law different from, or in addition to, the facts or law that the Company knows or believes to be true with respect to the claims released in this Separation Agreement and agrees, nonetheless, that this Separation Agreement and the release contained in it shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them.

2.6The Company declares and represents that it intends this Separation Agreement to be complete and not subject to any claim of mistake, and that the release herein expresses a full and complete release and Employee intends the release herein to be final and complete. The Company executes this release with the full knowledge that this release covers all possible claims against the Company Released Parties, to the fullest extent permitted by law

3.California Civil Code Section 1542 Waiver. The Parties expressly acknowledge and agree that all rights under Section 1542 of the California Civil Code are expressly waived. That section provides:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

4.Representation Concerning Filing of Legal Actions. The Parties represent that, as of the date of this Separation Agreement, neither Party has filed any lawsuits, charges, complaints, petitions, claims or other accusatory pleadings against the other Party or against any Employee Released Parties or Company Released Parties in any court or with any governmental agency.

5.Non-Disparagement. The Parties represent that as of the date of execution of this Separation, neither of them has, and that in the future, neither of them will make any voluntary statements, written, oral or electronic or cause or encourage others to make any such statements intended to defame, disparage or in any way criticize the personal and/or business reputations, practices or conduct of the other party or any of the other Employee Released Parties or Company Released Parties.

6.Confidentiality and Return of Company Property. Employee understands and agrees that as a condition of receiving the Separation Benefits in paragraph 2, all Company property must be returned to Company on or before the Separation Date. By signing this Separation Agreement, Employee represents and warrants that Employee will have returned to Company, on or before the Separation Date, all Company property, data and information belonging to Company and agrees that Employee will not use or disclose to others any confidential or proprietary

information of Company or the Employee Released Parties. In addition, Employee agrees to keep the terms of this Separation Agreement confidential, including the reasons for separation, between Employee and Company, except that Employee may disclose to attorney or accountant, if any, as needed and subject to confidentiality, but in no event will Employee discuss this Separation Agreement or its terms with any current or prospective employee of Company.

7.Continuing Obligations. Employee agrees to comply with the continuing obligations in the surviving provisions of Company's Confidential Information Agreement that Employee signed in connection with Employee's employment with Company.

8.Enforcement. In the event of a material breach by either Party of the terms of this Separation Agreement, any dispute arising therefrom shall be adjudicated by binding arbitration before a single neutral arbitrator in San Diego County, California. Any such arbitration shall be held before the American Arbitration Association and the Parties will jointly attempt to select a single neutral arbitrator. The AAA Rules for Commercial Disputes shall govern and if the Parties are unable to reach agreement on the selection of a single neutral arbitrator, the procedure for selection of the arbitrator set forth in the AAA Rules shall control. Nothing herein shall limit either Party's right to seek injunctive relief in the state or federal courts located in San Diego County, California. The costs of any arbitration hereunder shall be paid in accordance with the arbitration provisions contained in Employee's Offer Letter. Employee shall be entitled in any arbitration necessary to recover payments required under this Separation Agreement to recover legal fees. In all other respects, the parties shall each be responsible for payment of their own attorney's fees in arbitration.

9.No Other Severance. Employee acknowledges and agrees that the Severance provided pursuant to this Separation Agreement is in lieu of any other severance benefits to which Employee may be eligible under any other agreement and/or severance plan or practice.

10.No Admissions. By entering into this Separation Agreement, the Released Parties make no admission that they have engaged, or are now engaging, in any unlawful conduct. The parties understand and acknowledge that this Separation Agreement is not an admission of liability and shall not be used or construed as such in any legal or administrative proceeding.

11.Older Workers' Benefit Protection Act. This Separation Agreement is intended to satisfy the requirements of the Older Workers' Benefit Protection Act, 29 U.S.C. sec. 626(f) ("OWBPA"). Employee is advised to consult with an attorney before executing this Separation Agreement.

1.1Acknowledgments/Time to Consider. Employee acknowledges and agrees that (a) Employee has read and understands the terms of this Separation Agreement; (b) Employee has been advised in writing to consult with an attorney before executing this Separation Agreement; (c) Employee has obtained and considered such legal counsel as Employee deems necessary; (d) Employee has been given twenty-one (21) days to consider whether or not to enter into this Separation Agreement (although Employee may elect not to use the full 21-day period at Employee's option); and (e) by signing this Separation Agreement,

Employee acknowledges that Employee does so freely, knowingly, and voluntarily, and waives the 21 day consideration period.

1.1Revocation/Effective Date. This Separation Agreement shall not become effective or enforceable until the eighth day after Employee signs this Separation Agreement. In other words, Employee may revoke Employee's acceptance of this Separation Agreement within seven (7) days after the date Employee signs it. Employee's revocation must be in writing and received by Christine Zedelmayer, Chief Operating Officer by 5:00 p.m. Pacific Time on the seventh day in order to be effective. If Employee does not revoke acceptance within the seven (7) day period, Employee's acceptance of this Separation Agreement shall become binding and enforceable on the eighth day ("Effective Date").

1.2Preserved Rights of Employee. This Separation Agreement does not waive or release any rights or claims that Employee may have under the Age Discrimination in Employment Act that arise after the execution of this Separation Agreement. In addition, this Agreement does not prohibit Employee from challenging the validity of this Separation Agreement's waiver and release of claims under the Age Discrimination in Employment Act of 1967, as amended.

12.Severability. In the event any provision of this Separation Agreement shall be found unenforceable or unconscionable, the unenforceable provision shall be deemed deleted and the validity and enforceability of the remaining provisions shall not be affected thereby.

13.Full Defense. This Separation Agreement may be pled as a full and complete defense to, and may be used as a basis for an injunction against, any action, suit or other proceeding that may be prosecuted, instituted or attempted by Employee in breach hereof.

14.Applicable Law/Jurisdiction. The validity, interpretation and performance of this Separation Agreement shall be construed and interpreted according to the laws of the United States of America and the State of California. The Parties both acknowledge and agree that they are subject to the personal jurisdiction of the state and federal courts located within San Diego County, California.

15.Successors and Assigns. This Separation Agreement is binding on Employee's heirs, family members, executors, agents and assigns.

16.Counterparts. This Separation Agreement may be signed in counterparts, and each shall be treated as though signed as one document. This Separation Agreement shall not be binding upon the Parties until signed by both Parties hereto.

17.Recitals. The Recitals are hereby incorporated into and made part of this Separation Agreement.

18.Entire Agreement; Modification. This Separation Agreement, including the surviving provisions of the Company's Confidential Information Agreement previously executed by Employee and herein incorporated by reference, is intended to be the entire agreement between

Employee /s/ DT
Company /s/ BS

the parties and supersedes and cancels any and all other and prior agreements, written or oral, between the parties regarding this subject matter. This Separation Agreement may be amended only by a written instrument executed by all parties hereto.

THE PARTIES TO THIS SEPARATION AGREEMENT HAVE READ THE FOREGOING SEPARATION AGREEMENT AND FULLY UNDERSTAND EACH AND EVERY PROVISION CONTAINED HEREIN. WHEREFORE, THE PARTIES HAVE EXECUTED THIS SEPARATION AGREEMENT ON THE DATES SHOWN BELOW.

Dated: February 13, 2022 By: /s/ Dolca Thomas
Dolca Thomas

EQUILLIUM, INC.

Dated: February 13, 2022 By: /s/ Bruce Steel Bruce Steel, CEO

Employee /s/ DT
Company /s/ BS
DM2\15302614.1
DM2\15350807.1

ADDENDUM TO SEPARATION AGREEMENT DATED FEBRUARY 13, 2022

As of the date written below, the undersigned hereby reaffirms and ratifies the general release provisions contained in the February 13, 2022 Separation Agreement between herself ("Employee") and Equillium, Inc. ("the Company"), as follows:

1. Employee has received and will receive certain separation benefits pursuant to the February 13, 2022 Separation Agreement, which constitute good and sufficient consideration for the general release provided by Employee in the Separation Agreement and the general release provided by Employee herein.

2. Employee unconditionally, irrevocably and absolutely releases and discharges Company, and any parent and subsidiary corporations, divisions and affiliated corporations, partnerships or other affiliated entities of Company, including but not limited to Equillium AUS Pty Ltd. and with respect to each entity, all of its past and present employees, officers, directors, shareholders, agents, successors and assigns (collectively, "Employee Released Parties") from all claims related in any way to the transactions or occurrences between them to date, to the fullest extent permitted by law, including but not limited to Employee's employment with Company, the termination of Employee's employment, and all other losses, liabilities, claims, charges, demands and causes of action, known or unknown, suspected or unsuspected, arising directly or indirectly out of or in any way connected with Employee's employment with Company. This release is intended to have the broadest possible application and includes, but is not limited to, any local, state, or federal tort, contract, whistleblower, discrimination, harassment, retaliation, common law, constitutional or other statutory claims, including but not limited to alleged violations of the California Labor Code, California Industrial Welfare Commission wage orders, California Business and Professions Code, California Fair Employment and Housing Act, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, Section 1981 of the Civil Rights Act of 1866, the Equal Pay Act, the Genetic Information Nondiscrimination Act, and the Age Discrimination in Employment Act of 1967, as amended, any claims for wrongful termination and/or violation of public policy, any claims for breach of fiduciary duty, any claims for violation of Company and/or the Released Parties' bylaws, policies, procedures or other governing documents, and any and all claims for attorneys' fees, costs and expenses. This release shall not affect or modify Employee's rights to indemnification from the Company, if any, that may arise under her Offer Letter or statutory or common law as to any acts or omissions of Employee, during her employment and within the course and scope of that employment.

3. Employee acknowledges that Employee may discover facts or law different from, or in addition to, the facts or law that Employee knows or believes to be true with respect to the claims released in this Addendum to Separation Agreement and agrees, nonetheless, that this Addendum to Separation Agreement and the release contained in it shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them.

4. Employee declares and represents that Employee intends this Addendum to Separation Agreement to be complete and not subject to any claim of mistake, and that the release herein expresses a full and complete release and Employee intends the release herein to be final and

Employee __/s/ DT

Company __/s/ BS

complete. Employee executes this release with the full knowledge that this release covers all possible claims against the Employee Released Parties, to the fullest extent permitted by law.

5. This Addendum to Separation Agreement and the General Release contained herein is not intended to bar any claims that, by law, may not be waived, such as claims for workers' compensation benefits, unemployment insurance benefits, statutory indemnity, and any challenge to the validity of Employee's release of claims under the Age Discrimination in Employment Act of 1967, as amended, if applicable. This Addendum to Separation Agreement and the General Release contained herein does not prevent Employee from contacting, providing information to, or filing a charge with any federal, state or local government agency or commission, including but not limited to the Equal Employment Opportunity Commission ("EEOC"), the Securities and Exchange Commission ("SEC"), or the National Labor Relations Board ("NLRB"). Employee is prevented, however, to the maximum extent permitted by law, from obtaining any monetary or other personal relief for any of the claims Employee has released in this Paragraph 2 and its subparts with regard to any charge or claim Employee may file or which may be filed or otherwise brought on Employee's behalf. Nothing in this Addendum to Separation Agreement is intended to or shall be interpreted to restrict or otherwise interfere with: (i) Employee's obligation to testify truthfully in any forum; or (ii) Employee's right and/or obligation to contact, cooperate with, provide information to, or participate in any investigation conducted by, any government agency or commission (including but not limited to the EEOC, SEC or NLRB).

Executed this 21st day of February 2022 at San Francisco, California.

_/s/ Dolca Thomas_____
Dolca Thomas

Employee __/s/ DT
Company __/s/ BS

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 statement (No. 333-254656) on Form S-8, (No. 333-237407) on Form S-8, (No. 333-230536) on Form S-8, (No. 333-227859) on Form S-8, and (No. 333-234683) on Form S-3 of our report dated March 23, 2022, with respect to the consolidated financial statements of Equillium, Inc.

/s/ KPMG LLP

San Diego, California
March 23, 2022

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 23, 2022

/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 23, 2022

/s/ Jason A. Keyes
Jason A. Keyes
Chief Financial Officer
(Principal Financial and Accounting 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, 2021, 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 23, 2022

/s/ Jason A. Keyes
Jason A. Keyes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 23, 2022

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.