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, 2019

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 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 28, 2019 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $33.7 million based on the closing price of the registrant's common stock on June 28, 2019 of $5.66 per share, as reported by the Nasdaq Global Market.

As of March 23, 2020, there were 17,618,591 shares of the registrant's common stock outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our plans to research, develop and commercialize itolizumab (EQ001) and any future product candidates;
- our ability to obtain and maintain regulatory approval of itolizumab (EQ001) in any of the indications for which we plan to develop it;
- our ability to obtain funding for our operations, including funding necessary to commence and complete the clinical trials of itolizumab (EQ001);
- the success, cost, and timing of our product development activities, including our ongoing and planned clinical trials of itolizumab (EQ001);
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize itolizumab (EQ001);
- the rate and degree of market acceptance of itolizumab (EQ001);
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States;
- the performance of our third-party 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 itolizumab 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.

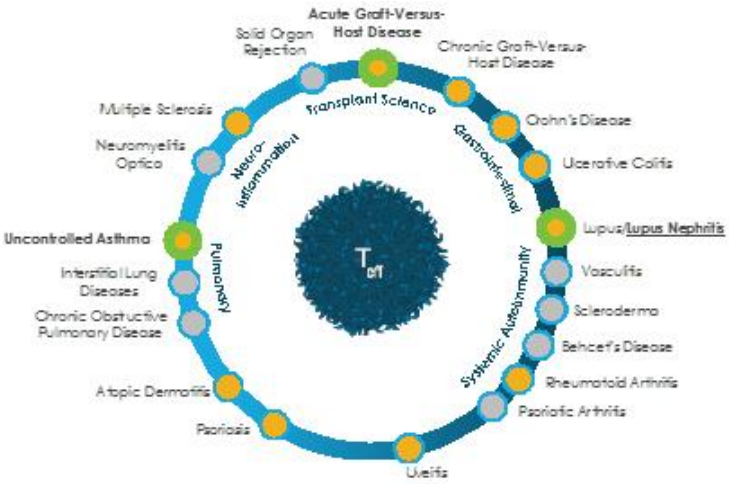
PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products 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. Activated T_{eff} cells drive a number of immuno-inflammatory diseases across therapeutic areas including transplant science, systemic autoimmunity, pulmonary, neurologic, gastrointestinal, renal, vascular, ophthalmic and dermatologic disorders. Therefore, we believe itolizumab may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.

T cell mediated diseases*



* We are focusing our initial development efforts on itolizumab (EQ001) for the treatment of the diseases underlined in bold and are evaluating additional T cell driven indications for future development.

Our pipeline is focused on developing itolizumab (EQ001) as a potential best-in-class, disease modifying treatment for multiple severe immuno-inflammatory disorders. Our Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, for acute graft-versus-host disease, or 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 a Phase 1b/2 clinical trial of itolizumab (EQ001) for the treatment of aGVHD. In June 2019, we initiated a Phase 1b proof-of-concept clinical trial in Australia for the treatment of uncontrolled asthma. Our IND for lupus nephritis was accepted by the FDA in July 2019, and we initiated a Phase 1b proof-of-concept clinical trial for the treatment of lupus nephritis in September 2019. The FDA granted itolizumab (EQ001) Fast Track designation for the treatment of lupus nephritis in December 2019. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma and our Phase 1b clinical trial of itolizumab (EQ001) in 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. We are continuing to enroll 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.

The following chart summarizes the status of our current clinical development of itolizumab (EQ001).

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. Our selection of current and future indications is driven by our analysis of the scientific, translational, clinical and commercial rationale for advancing itolizumab (EQ001) into further development.

We acquired rights to itolizumab (EQ001) for the territories of the United States and Canada in May 2017 pursuant to a collaboration and license agreement with Biocon SA (subsequently assigned to Biocon Limited, or together, Biocon), and the territories of Australia and New Zealand in December 2019 pursuant to an amendment to that agreement. Following completion of a Phase 3 clinical trial conducted by Biocon outside of North America, itolizumab (EQ001) was approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon in India as ALZUMAb. Today, India is the only jurisdiction where ALZUMAb is approved or marketed. Our partnership 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 FDA. In August 2019, we entered into an 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 agreement allows us to represent itolizumab (EQ001) more broadly commercially and participate in value that may be created with strategic partners across geographies.

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 uncontrolled asthma.** Asthma is a heterogeneous immuno-inflammatory disease for which T_{eff} cells such as T_h2 and T_h17 play a central role in immunopathogenesis. Targeting the CD6-ALCAM pathway with itolizumab (EQ001) has been shown to inhibit the activity and trafficking of both T_h2 and T_h17 T_{eff} cells. Therefore, we believe itolizumab (EQ001) is uniquely positioned to broadly address both T_h2-mediated eosinophilic and non-T_h2-mediated non-eosinophilic asthma. Current biological therapies that are approved and most of the new agents in development for asthma have focused on patients with eosinophilic T_h2-driven asthma and don't address a large portion of the population with non-eosinophilic or non-T_h2 asthma. Our development strategy will be to address these gaps in care by assessing activity of itolizumab (EQ001) in uncontrolled asthma patients with both eosinophilic and non-eosinophilic asthma. We initiated a Phase 1b proof-of-concept clinical trial of itolizumab (EQ001) in patients with uncontrolled asthma in June 2019. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma. 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.

- **Develop itolizumab (EQ001) for the treatment of GVHD.** Based on our deep and proprietary understanding of the CD6-ALCAM pathway, our translational research, and prior clinical studies targeting CD6+ T_{eff} cells in graft-versus-host disease, or GVHD, we are developing itolizumab (EQ001) for the frontline treatment of aGVHD. Itolizumab (EQ001) blocks the CD6-ALCAM pathway thereby inhibiting T_{eff} cell activity and trafficking into tissues. We initiated a Phase 1b/2 clinical trial of itolizumab (EQ001) as a front-line therapy concomitant with steroids for the treatment of aGVHD and expect topline data from the Phase 1b part of this trial in the second half of 2020. In this trial we are assessing safety, pharmacokinetics, or PK, pharmacodynamics, or PD, and a number of clinical outcomes including overall response rate, survival, steroid taper and incidence of chronic GVHD, or cGVHD. Based on input from our clinical advisors, we have decided to take a sequential approach to developing itolizumab (EQ001) in GVHD as we contemplate expanding the program. Learnings from the Phase 1b portion of the aGVHD trial will inform our clinical development strategy that includes a broader life-cycle approach, potentially including cGVHD, as well as the prevention of GVHD. We believe that this sequential approach enables a more efficient and optimized development program in GVHD.

- **Develop itolizumab (EQ001) for the treatment of lupus nephritis.** Itolizumab **(**EQ001) has been shown to block the CD6-ALCAM pathway thereby inhibiting T_{eff} cell activity and trafficking into tissues. Translational data in preclinical models of lupus and glomerulonephritis, plus data from human kidney and urine samples, supports targeting the CD6-ALCAM pathway in lupus nephritis. We believe that itolizumab (EQ001) represents a promising therapeutic approach that is highly differentiated relative to B cell, single cytokine and other co-stimulatory therapies that have largely failed in attempts to develop treatments for lupus and lupus nephritis. We initiated a Phase 1b proof-of-concept clinical trial of itolizumab (EQ001) in patients with lupus nephritis in September 2019. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in 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. As part of the early development program in lupus nephritis, we may also include the co-development and validation of a diagnostic biomarker related to the CD6-ALCAM pathway and other urinary biomarkers to further evaluate and support a potential companion diagnostic strategy.

- **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).

- **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, such as uncontrolled asthma, 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**.

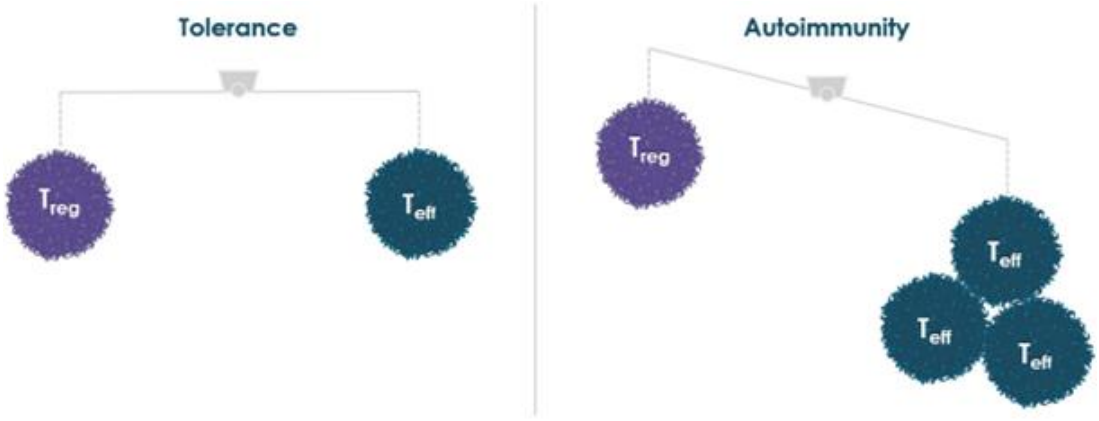


Figure 1: Autoimmunity is a balancing act. Treg cells play an important role in preventing Teff cells targeting of self-antigens that can lead to autoimmunity and tissue destruction.

Immune checkpoints are critical regulators of immune activation pathways and can be either co-stimulatory (activating) or co-inhibitory (inhibiting). These pathways are crucial for maintaining immune balance and preventing autoimmunity. Immune checkpoints have been targeted for the treatment of cancers, where blockade of co-inhibitory signals results in an increased immune response against tumor cells, and such approaches have resulted in the approval of several novel therapeutics. 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. However, identifying checkpoints that allow for the selective modulation of T_{eff} cell activity while preserving T_{reg} cell activity in order to promote tolerance has proven challenging.

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 lack of expression of CD6 on T_{reg} cells suggests that CD6 is not required for their regulatory function. See **Figure 2.**

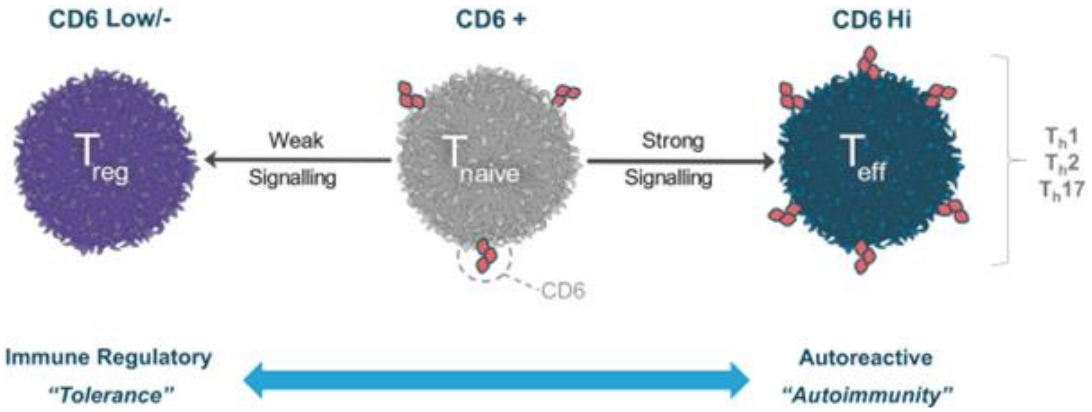


Figure 2: CD6, a novel, tightly-regulated, co-stimulatory checkpoint central to autoimmunity. The expression levels of CD6 are increased on Teff cells such as Th1, Th2 and Th17 cells and are associated with autoreactivity. Conversely, the lack of expression of CD6 on Treg cells suggests that CD6 is not required for their regulatory function.

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, or MAPK, 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.

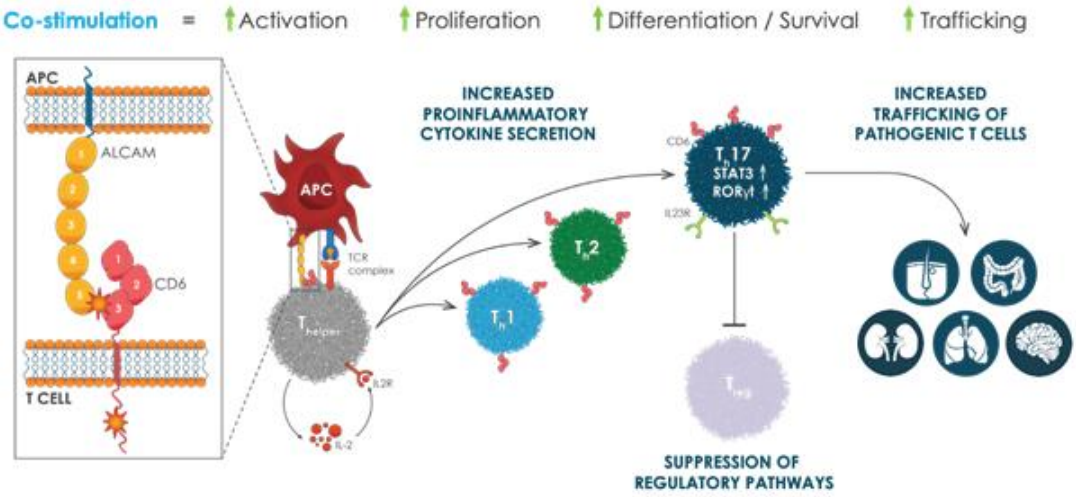


Figure 3: CD6 co-stimulation drives pathogenic T cell development and activity. Co-stimulation occurs through the binding of ALCAM to domain-3 of CD6, leading to synergistic activation resulting in a five-fold increase in IL-2 receptor mediated Teff cell proliferation. Co-stimulation through CD6 promotes a pro-inflammatory response including the activation of pSTAT3 and RORγt resulting in increased expression of IL-23R and pathogenic secretion of several Teff pro-inflammatory cytokines. ALCAM expressed on tissues such as the skin, lung, gut, blood-brain-barrier and kidney, selectively facilitates the trafficking of Teff cells expressing CD6. Notably, Th17 cells (that are steroid insensitive) and associated cytokines suppress Treg cell activity leading to a high Th17:Treg 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. See **Figure 4**.

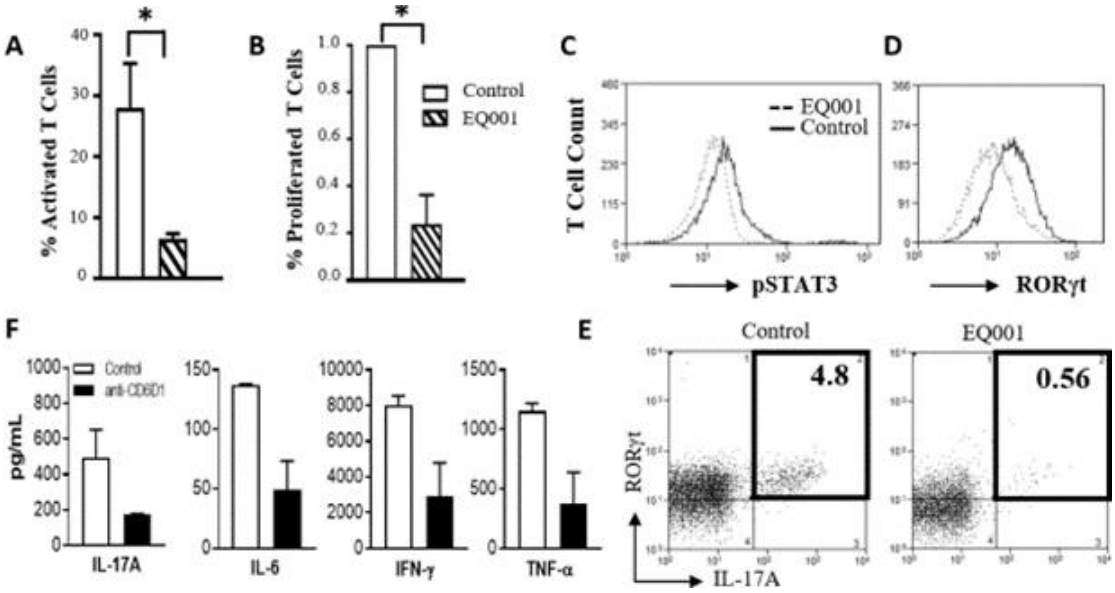


Figure 4: Blockade of CD6 reduces T cell activation, proliferation and differentiation. (A-C) Human peripheral blood mononuclear cells, or PBMC, were stimulated in Th17 polarizing conditions in the presence of itolizumab (EQ001) or a control antibody. On Day 3 post-stimulation, itolizumab (EQ001) reduced the percentage of activated T cells, shown in panel A, and the percentage of proliferating T cells, shown in panel B. Itolizumab (EQ001) also reduced levels of pSTAT3, a Th17 signature transcription factor, shown in panel C. (D and E) PBMC cells were re-stimulated with PMA-Ionomycin for five hours and analyzed for expression of intracellular cytokine IL-17A and another Th17 signature transcription factor RORγt. Day 6 representative histogram of RORγt is shown in panel D and the corresponding dot plots of RORγt and IL-17A gated on lymphocyte scatter and CD3 expressing T cells are shown in panel E. (F) Splenocytes were isolated from mice treated with anti-CD6D1, a mouse surrogate anti-CD6 antibody, or a control antibody and stimulated *ex vivo*. Anti-CD6D1 treatment resulted in a substantially reduced response to stimulation and the splenocytes secreted lower levels of pro-inflammatory T cell cytokines IL-17A, IL-6, IFN-γ and TNF-α, shown in panel F. *p<0.05.

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 5**.

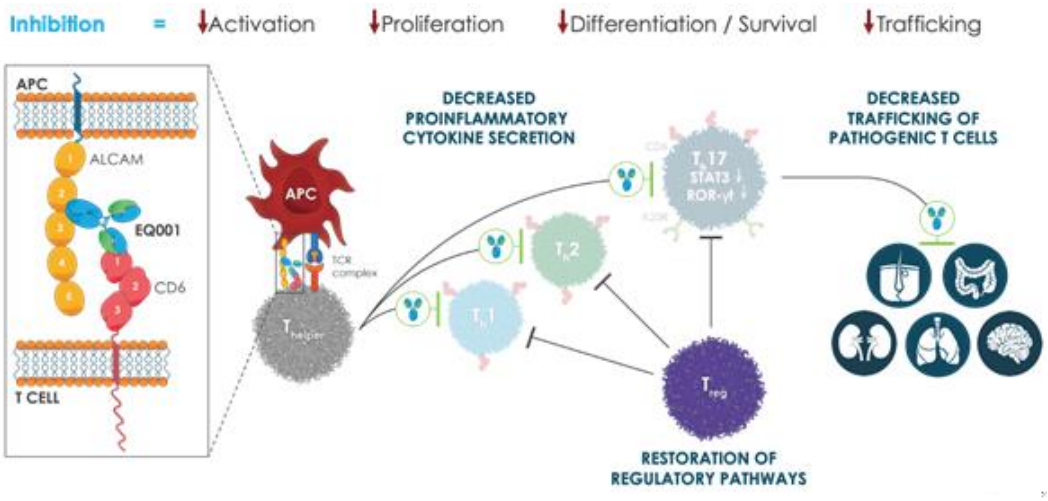


Figure 5: Blockade of CD6 by itolizumab (EQ001) inhibits Teff cell activation, proliferation, differentiation and trafficking. Itolizumab **(**EQ001) selectively binds to domain-1 of CD6 and inhibits the interaction of ALCAM, preventing co-stimulation and thereby reducing Teff cell proliferation. Blockade of CD6 downregulates pSTAT and RORγt resulting in reduced expression of IL-23R and secretion of pro-inflammatory Teff 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 Th17 cells inhibiting the Treg cells restores immune balance and promotes immune tolerance.

Experimental Evidence for Targeting CD6 in Immuno-Inflammation

We are leveraging our deep understanding of immunobiology and translational biology program to assess the importance of the CD6-ALCAM pathway in disease pathogenesis and therapeutic utility of CD6 blockade using well-characterized model systems and human tissues. As a leader in the field of CD6 immunobiology, our objective is to inform selection of indications in specific disease areas that are likely to respond to the targeting of the CD6-ALCAM pathway by itolizumab (EQ001).

The role of CD6 in pathogenic T_{eff} cell development has been independently validated *in vivo* both genetically and pharmacologically in experimental models of T_h1, T_h2 and T_h17 immuno-inflammation, as summarized in **Table 1**.

Table 1: Published, independent studies supporting the role of CD6 in immuno-inflammatory diseases.

ANIMAL MODEL/INDICATIONS	METHOD	RESULTS & CONCLUSIONS
Experimental Atopic Dermatitis ***Oh et al. 2019*** ***Allergy, Asthma & Immunology Research***	ALCAM-/- mouse†	▪ Decreased clinical disease scores* ▪ Decreased Th2 cytokines (IL-4, IL-5 and IL-13) ▪ Decreased Th1/ Th17 cytokines (IFNγ, IL-17) ▪ Decreased CD4 T cell activation*
Experimental OVA-induced Allergy ***Kim et al., 2018*** ***Clinical & Experimental Immunology***	ALCAM-/-	▪ Decreased pro-inflammatory Th2 cell responses* ▪ Decreased disturbance of intestinal tissue ▪ Decreased Th2 cytokines (IL-4, IL-5 and IL-13)
	anti-mouse CD6	▪ Decreased T cell proliferation*
Experimental OVA-induced Asthma ***Kim et al. 2018*** ***American Journal of Respiratory & Critical Care Medicine***	ALCAM-/- mouse†	▪ Decreased pro-inflammatory Th2 cell responses* ▪ Decreased T cell trafficking into the lung
	Mouse anti-CD6D1**	▪ Decreased T cell proliferation*
Experimental Autoimmune Uveitis ***Zhang et al. 2018*** ***Journal of Autoimmunity***	CD6-/- mouse†	▪ Decreased retinal inflammation (80% reduction in the mean histopathological scores)* ▪ Decreased autoreactive T cell responses (>70% reduction in Th1 and Th17 cytokine production)*
	Mouse anti-CD6D1**	▪ Decreased retinal inflammation (80% reduction in the mean histopathological scores)* ▪ Decreased T cell infiltration in the eyes (79% reduction in infiltrating T cell numbers)*
Experimental Autoimmune Encephalomyelitis **Multiple Sclerosis, Neuromyelitis Optica, Acute Disseminated Encephalomyelitis** ***Li et al. 2017*** ***Proceedings of the National Academy of Sciences***	CD6-/- mouse†	▪ Decreased clinical disease scores* ▪ Decreased pathogenic T cell responses (significant reduction in Th1 and Th17 cytokine production)* ▪ Blocked pathogenic T cell infiltration into the CNS
	Mouse anti-CD6D1**	▪ Decreased clinical disease scores* ▪ Decreased Th1 and Th17 cell responses* ▪ Decreased inflammation and demyelination in the CNS
Imiquimod-induced Psoriasis ***Consuegra-Fernandez et al. 2017*** ***Cellular and Molecular Immunology***	CD6-/- mouse†	▪ Decreased skin inflammation (epidermal thickness)* ▪ Decreased pro-inflammatory cytokines* ▪ Decreased Th17 cell differentiation *in vitro**

† CD6-/- is a mouse with a homozygous null gene deletion of CD6. ALCAM -/- is a mouse with a homozygous null gene deletion of ALCAM.
* Represents a statistically significant result ($p<0.05$).
** Mouse surrogate anti-CD6 antibody.

In addition to these published studies, we have demonstrated the activity of itolizumab (EQ001) (or anti-CD6D1, its mouse surrogate anti-CD6 antibody) in a number of disease models. Described below are findings from studies in models of several key immuno-inflammatory disease areas, including GVHD, inflammatory bowel disease, neuroinflammation, systemic lupus erythematosus, or SLE, and glomerulonephritis, which illustrate blockade of CD6 inhibiting pathogenic T cell activity. We believe the results of these published studies and our internal translational program support our approach in targeting the CD6-ALCAM pathway in the treatment of immuno-inflammation.

Treatment with itolizumab (EQ001) Attenuates GVHD

GVHD is a multisystem disease commonly associated with hematopoietic stem cell transplants in which transplanted donor lymphocytes attack host tissues. GVHD is predominantly driven by T cells that express high levels of CD6. Prior clinical studies have implicated cells expressing CD6 in the development of GVHD, suggesting that CD6 is a highly relevant target to this disease.

The Hu-PBMC-NSG model is a humanized xenograft mouse model of GVHD generated by injection of human peripheral blood mononuclear cells, or Hu-PBMC, into an NSG mouse, which is an immunodeficient mouse. In this well-characterized, gold standard model, disease is aggressively driven by a human T cell response against host tissue. The severity of disease is assessed by survival, weight loss, prevalence of human cells in peripheral blood and trafficking of human cells into tissues. Itolizumab (EQ001) can be assessed in this model because human T cells are present. In the model, we tested a high dose of itolizumab (EQ001) (300µg/dose), a low dose of itolizumab (EQ001) (60µg), and as comparator controls, two CTLA4-Ig based modulators of CD28 co-stimulation, Nulojix (belatacept) and Orencia (abatacept), which are both FDA-approved drugs that also target activated T_{eff} cells.

Treatment with both high and low dose itolizumab (EQ001) resulted in no deaths by Day 35 compared to the 90% mortality seen in vehicle treated control animals. See **Figure 6.** This is a direct result of inhibition of human T cell proliferation and infiltration into tissues. Animals treated with itolizumab (EQ001) demonstrated a profound reduction in human T cells at Days 10 and 35 with a prevalence of 0.2% (both days), whereas vehicle treated animals exhibit a prevalence of 17.5% human T cells by Day 10. The ability of itolizumab (EQ001) to prevent T cell establishment compared highly favorably to both Nulojix and Orencia.

Itolizumab (EQ001) was similarly able to control ongoing GVHD disease that was initiated before the start of treatment with itolizumab (EQ001). See **Figure 7**. Treatment with itolizumab (EQ001) starting 5 days after disease initiation resulted in a ~50% reduction in mortality and significant decrease in weight loss compared to vehicle control animals. These results were matched by decreases in peripheral T cell prevalence compared to vehicle control animals demonstrating the potential for the use of itolizumab (EQ001) as a prophylactic and therapeutic approach to managing GVHD.

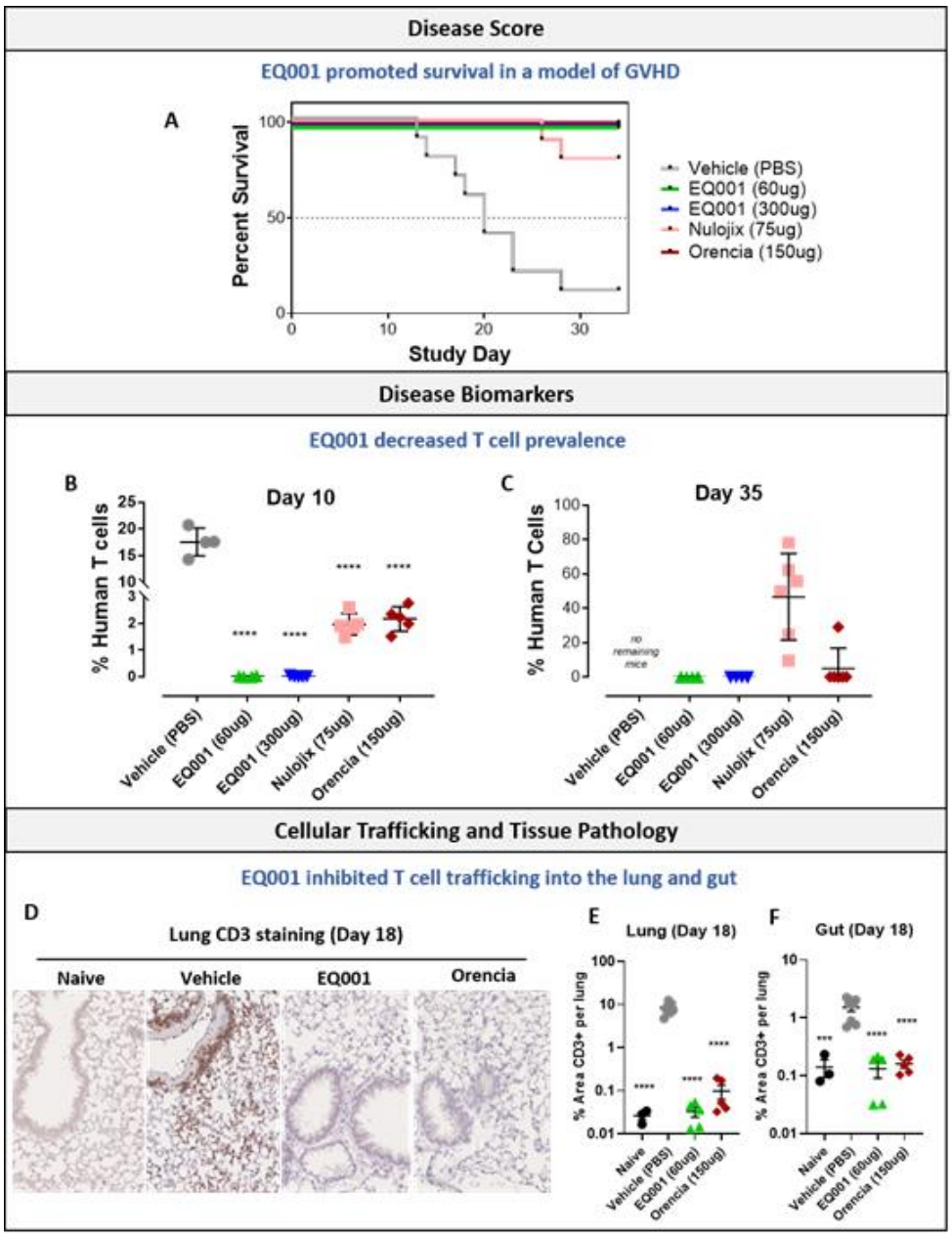


Figure 6: Treatment with itolizumab (EQ001) attenuates GVHD. (A) Kaplan-Meier survival curve of mice treated with either itolizumab (EQ001), Nulojix, Orencia or vehicle prior to injection with human PBMCs. Mice treated with itolizumab (EQ001) experienced 100% survival. (B and C) Proportion of human T cells detected in the periphery was statistically significantly lower in Hu-NSG-PBMC mice treated with itolizumab (EQ001) vs. vehicle control at Day 10 (B) and remains low at Day 35 (C). (D) CD3 staining in lung tissue shows infiltration of T cells in vehicle-treated mice but not itolizumab (EQ001)-treated mice. (E and F) Quantitation of T cell infiltration in the lungs and gut at Day 18 demonstrated that mice treated with itolizumab (EQ001) had statistically significantly lower levels of infiltrated T cells compared to vehicle control mice and were comparable to naïve (non-GVHD) mice. ****p<0.0001 and ***p<0.001.

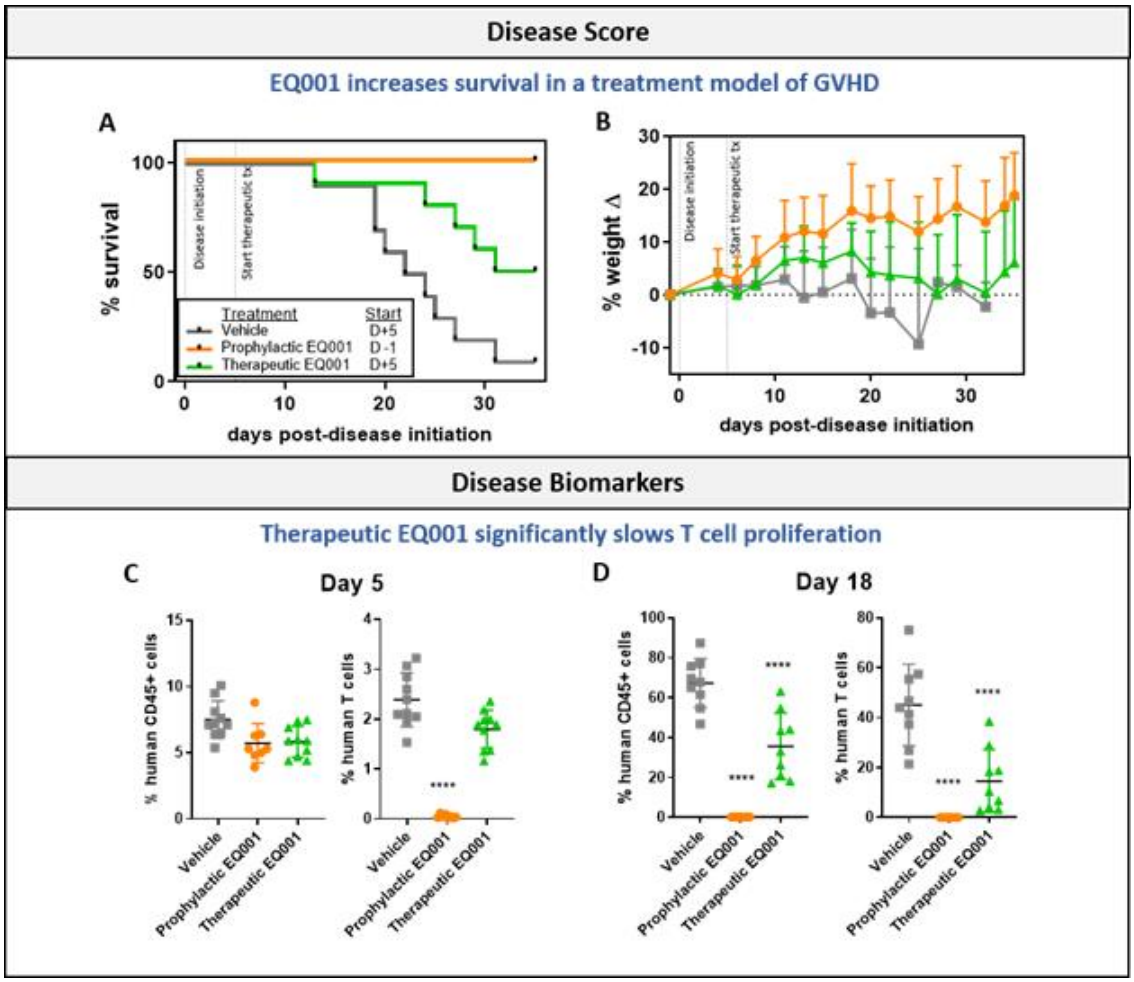


Figure 7: Therapeutic treatment with itolizumab (EQ001) improves survival in GVHD. Hu-NSG-PBMC mice were treated with itolizumab (EQ001) or vehicle one day prior (prophylactic) or 5 days after (therapeutic) disease initiation. Therapeutic treatment with itolizumab (EQ001) significantly reduced mortality as shown in the Kaplan-Meier survival curve (p=0.0245) (A) as well as decreased disease-associated weight loss (B). (C) Just before the start of dosing at Day 5, the prevalence of human T cells in the periphery was similar except in the group that had already begun prophylactic treatment with itolizumab (EQ001) which exhibited significantly lower T cell prevalence. (D) By Day 18, mice therapeutically-treated with itolizumab (EQ001) demonstrated statistically significantly lower T cell levels vs. vehicle control. ****p<0.0001.

Treatment with Anti-CD6 Antibody Inhibits Inflammatory Bowel Disease

Inflammatory bowel disease, or IBD, such as Crohn's disease and ulcerative colitis, is characterized by chronic inflammation resulting from persistent activation and infiltration of immune cells in the gut. Activated T_{eff} cells, such as T_h1 and T_h17, which express CD6, are associated with IBD and its severity. Data from human genetic studies have demonstrated an association between CD6 and the development and severity of IBD. Translational data demonstrates that ALCAM expression is increased in intestinal mucosa of IBD patients and correlates with an increased infiltration of CD6+ T_h1/T_h17 T cells and disease severity. Additionally, increased IFN-γ and IL-17A expression in IBD patients is associated with CD6+ T_{eff} cells. Inhibition of T_{eff} cells, such as T_h1 and T_h17 cells, have been shown to reduce IBD disease severity and progression, confirming the relevance of the CD6-ALCAM pathway in this disease.

The 2,4,6-trinitrobenzenesulfonic acid, or TNBS, model is a standard model of IBD that is driven by T_h1 and T_h17 cell responses. Exposure to TNBS leads to inflammation, diarrhea, tissue destruction and shortening of the colon. In this model, we tested blockade of CD6 using anti-CD6D1, which binds to the same CD6 domain-1 in mice that itolizumab (EQ001) binds on human CD6. As comparator controls, separate groups of mice were treated with either anti-IL-12p40 (a therapeutic mechanism of action similar to Stelara, an FDA-approved therapy for Crohn's disease), dexamethasone or vehicle. Blockade of CD6 inhibits the TNBS-induced immune response as exhibited by decreases in serum and tissue pro-inflammatory cytokines, see **Figure 8**. This is accompanied by statistically significant decreases in inflammation-mediated colon shrinkage, histological measures of necrosis, edema and mucosal inflammation, and diarrhea/loose stool. The results of anti-CD6D1 treatment were comparable to high dose anti-IL-12p40 treatment, another inhibitor of the T_h1 and T_h17 cell pathways. Results of this model are relevant not only to IBD but also other immuno-inflammatory gut conditions, including GVHD.

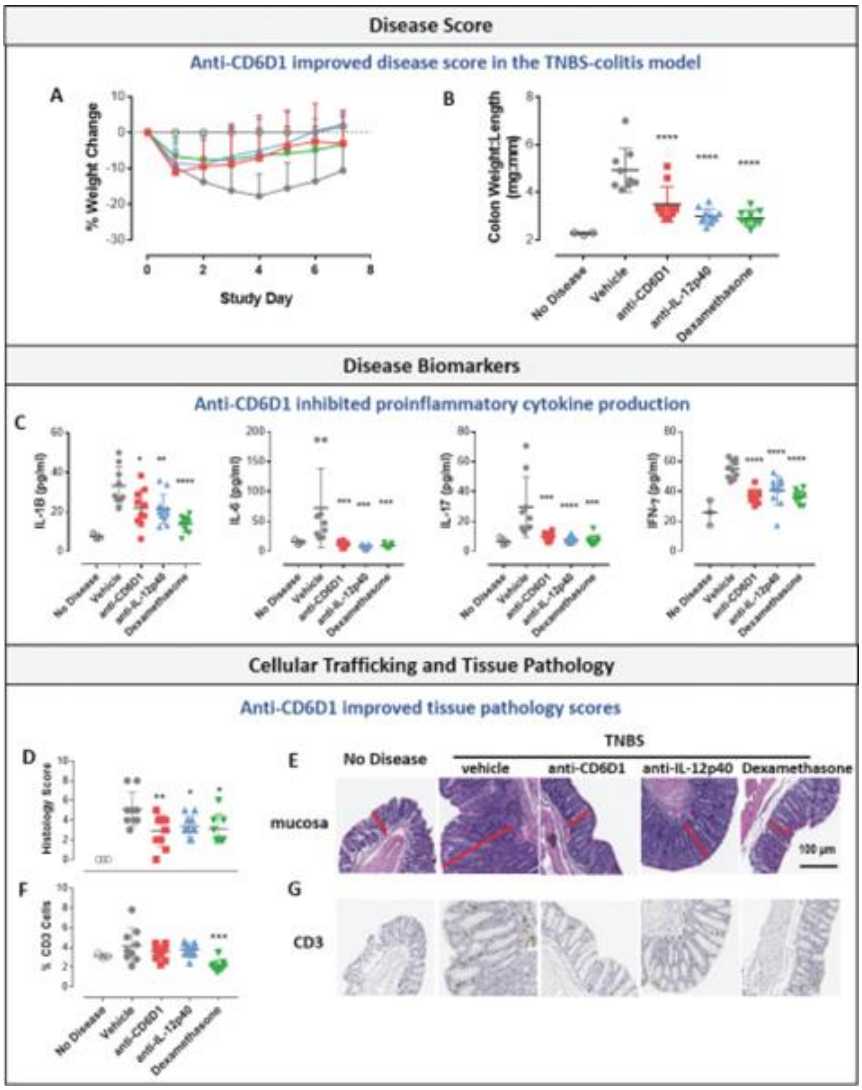


Figure 8: Treatment with anti-CD6D1 inhibits inflammatory bowel disease. (A and B) Anti-CD6D1 treatment decreased disease scores as measured by (A) a reduction in body weight loss and (B) the statistically significant reduction of colon weight to length ratio compared to vehicle control. (C) CD6 blockade decreased serum pro-inflammatory cytokines. (D and E) Tissue pathology scores were statistically significantly improved by anti-CD6D1 treatment. Red line denotes width of colon mucosa, delineating mucosal hyperplasia (tissue thickening). Hyperplasia was greatest in vehicle animals and was reduced in anti-CD6D1, anti-IL-12p40 and dexamethasone treated animals. (F and G) Anti-CD6D1 treatment reduced trafficking of T cells into the colon, as demonstrated by CD3, a pan T cell marker. ****p<0.0001, ***p<0.001, **p<0.01 and *p<0.05.

Treatment with Anti-CD6 Antibody Reduces Neuroinflammation

CD6 is overexpressed on activated T_h17 cells isolated from multiple sclerosis patients and has been implicated in the pathogenesis of neuroinflammation. On the vascular endothelium of the blood-brain-barrier, ALCAM is upregulated by IFN-γ, providing a potential mechanism for the entry of T cells expressing CD6 into the central nervous system, or CNS. Increased levels of CD6 are correlated to increased infiltration of T_{eff} cells into the CNS and the development of neuroinflammation. These data support the role of the CD6-ALCAM pathway in the pathogenesis of neuroinflammatory diseases such as multiple sclerosis.

Experimental autoimmune encephalomyelitis, or EAE, is a well-established mouse model of neuroinflammation that is commonly used to study disorders such as multiple sclerosis and neuromyelitis optica. In this model, an autoimmune response leads to T cell infiltration across the blood-brain barrier and into the tissues of the CNS (including spinal cord and optic nerve). Mice with EAE exhibit muscle weakness progressing to paralysis due to increasing neuronal damage. Blockade of CD6 by anti-CD6D1 results in reduced disease severity as demonstrated by statistically significant improvements in disease model scores (i.e., less weakness and paralysis), decreased autoimmune T cell activity and decreased T cell trafficking, resulting in decreased demyelination of the spinal cord, see **Figure 9**.

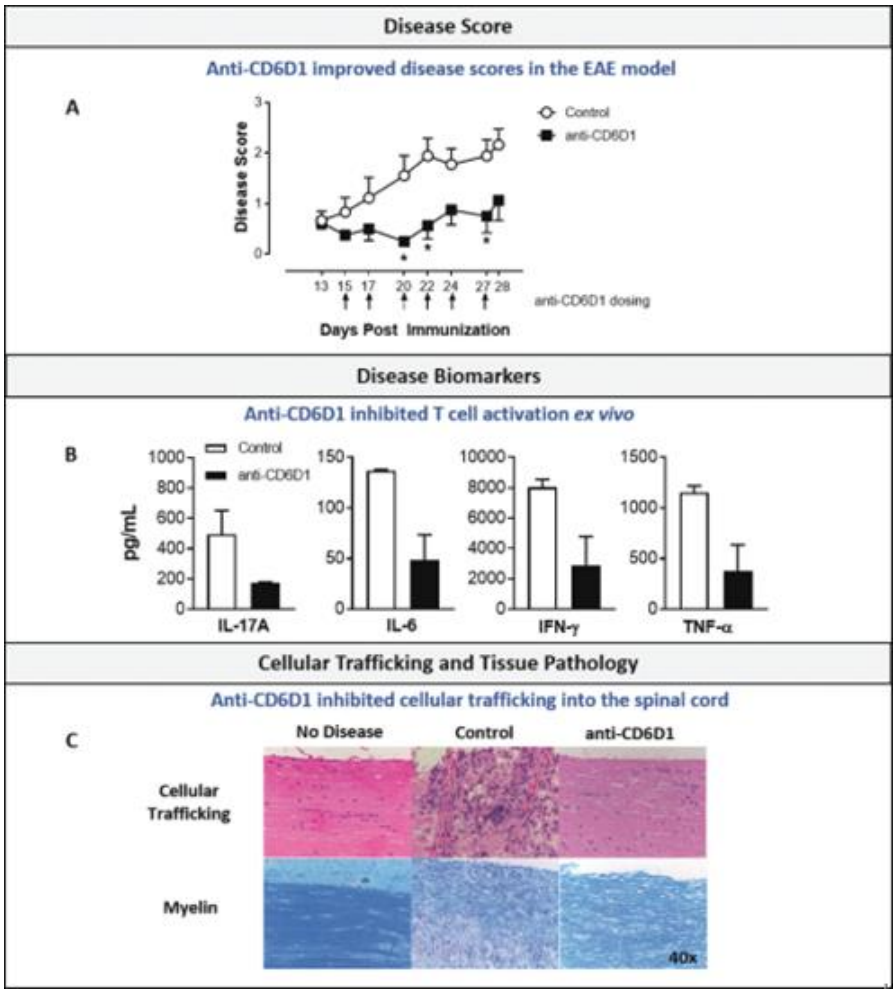


Figure 9: Treatment with anti-CD6D1 attenuates neuroinflammation. (A) Antagonism of the CD6 pathway during EAE induction results in statistically significant decreases in disease model scores. (B) Isolated T cells stimulated *ex vivo* exhibit a substantially reduced response to stimulation, secreting lower levels of important T cell cytokines IL-17A, IL-6, IFN-γ, and TNF-α. (C) Amelioration of EAE is supported by decreased cellular trafficking into the spinal cord and reduced demyelination. Anti-CD6D1 treated animals appear similar to normal, disease-free animals. *p<0.01.

Treatment with Anti-CD6 Antibody Inhibits Renal Inflammation

Recent evidence has demonstrated that T_{eff} cells specifically play a crucial role in the pathogenesis of both SLE and lupus nephritis by mediating tissue damage and the production of autoantibodies via promotion of B cell maturation and activity. Multiple T_{eff} cells, T_h1, T_h2, T_h17 as well as CD8 T cells, have all been implicated in the immune pathogenesis of both SLE and lupus nephritis. However, T_h17 cells are emerging as key targets. 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 in T_{reg} cells, suggesting that loss of this functional immune balance may be involved in the pathogenesis of renal damage in SLE patients.

To test the effect of CD6 blockade in an extensively tested model of SLE and lupus nephritis, we utilized the MRL/MpJ-Faslpr/2J mouse strain. This strain develops spontaneous systemic autoimmunity with many similarities to human SLE and lupus nephritis disease and is routinely used in SLE/lupus nephritis research. Analogous to SLE patients, mice develop systemic autoimmunity, hyperactive T and B cells, autoantibodies against nuclear antigens, glomerulonephritis, and additional SLE manifestations including arthritis, cerebritis, skin rash, and vasculitis. In this model, we tested anti-CD6D1 antibody, isotype control, vehicle or cyclophosphamide (similar mechanism as Cytoxan).

Blockade of CD6 using anti-mCD6D1 reduced mortality due to systemic autoimmunity. Both proteinuria and the ratio of urine albumin and creatinine at termination (more accurate measure of kidney function) were significantly reduced, indicating better kidney function compared to controls (Figure 10). This was matched by decreased numbers of infiltrating T cells in the kidney, including effector/memory and activated CD4 and CD8 T cells, which are thought to play a pathogenic role in this model as well as human lupus nephritis disease. Tissue damage as measured by renal pathology and skin lesions were significantly decreased similarly to cyclophosphamide, which is one of the few effective, albeit relatively toxic, treatments for lupus nephritis (Figure 10).

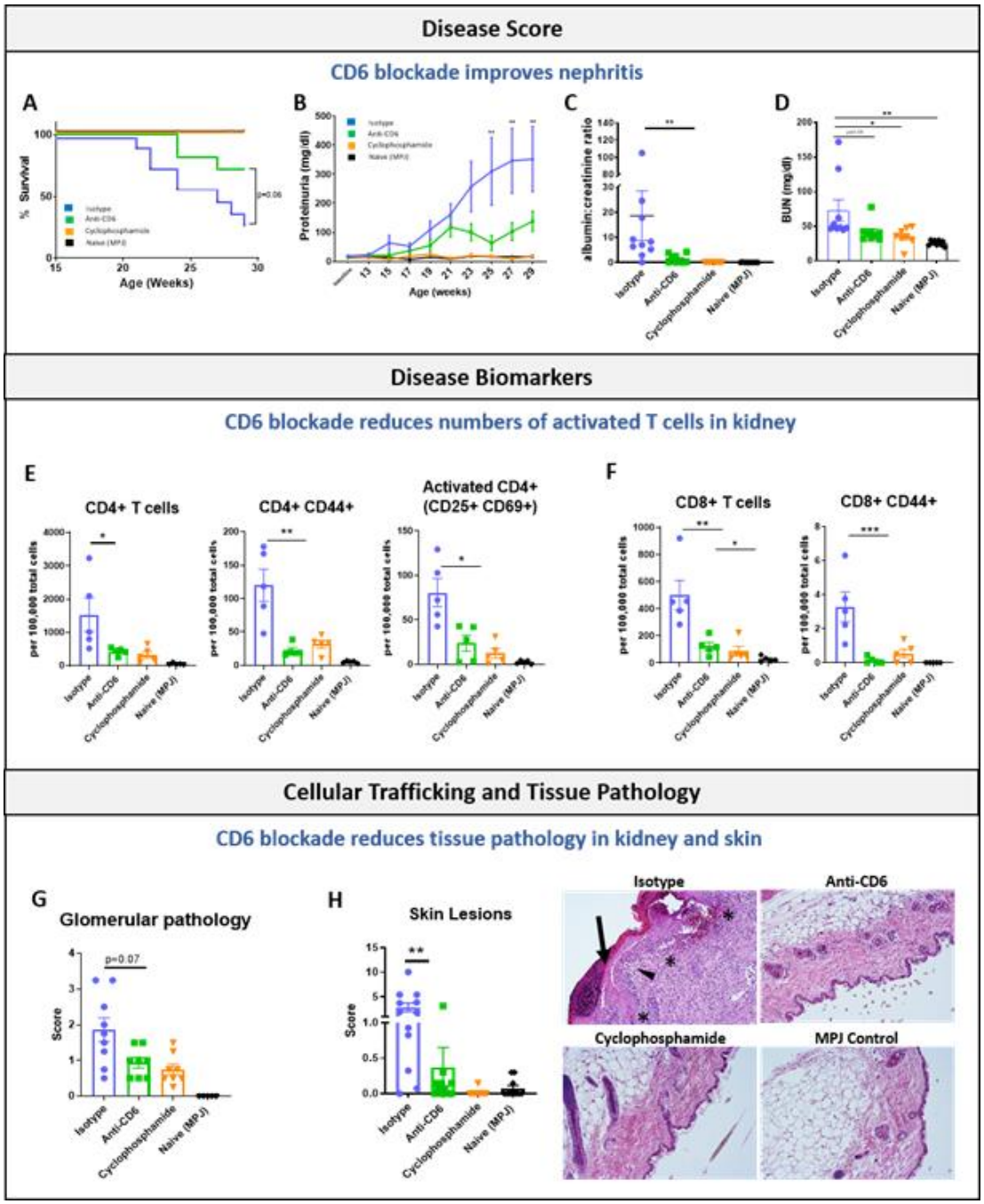


Figure 10: CD6 blockade in a spontaneous murine model of SLE and lupus nephritis inhibits both non-renal and renal disease manifestations .(A) Kaplan-meier curve depicting survival by treatment group. (B) Longitudinal proteinuria as measured by uristix. (C) urine albumin:creatinine ratio and (D) Blood urea nitrogen levels at termination (week 29). (E-F) Prevalence of kidney infiltrating CD4 T cells (E) and CD8 T cells (F) at termination. (G) Scoring of glomerular pathology at termination. (H) Macroscopic skin scoring at termination (graph) and histology (images). **** p<0.001; ** p<0.01; * p<0.05*

To further examine the role of CD6 blockade specifically on renal inflammation associated lupus nephritis, we utilized a well-characterized model of acute glomerulonephritis that is commonly used to study lupus nephritis. The nephrotoxic serum nephritis, or NTN, model exhibits glomerulonephritis that is mechanistically and histologically similar to that observed with lupus nephritis and, consequently, the NTN model is commonly used to test pharmacologic agents for this specific complication of SLE. Similar to the MRL/MpJ-Faslpr/2J model of SLE (described above), we tested anti-CD6D1 antibody, isotype control, vehicle or cyclophosphamide (similar mechanism as Cytoxan).

Anti-mCD6D1 treated mice maintained significantly lower proteinuria compared to isotype and vehicle control mice (Figure 11A). At termination, the albumin creatinine ratios, or ACRs, were significantly lower in anti-mCD6D1 treated mice (Figure 11B). Furthermore, blood urea nitrogen, a second measure of kidney function in serum, was decreased, suggesting that CD6 blockade protected kidney function in this model (Figure 11C). The improvement in kidney function was associated with a decrease in immune cell infiltration, with fewer infiltrating total lymphocytes (CD45+), CD11b+ myeloid cells, inflammatory macrophages, neutrophils, and T cells in the kidney (Figure 11E). T cells play an important role in the pathogenesis of nephritis and kidney damage. Importantly, the prevalence of activated CD4 T cells (CD25+ CD69+) was also diminished (Figure 11E). The reduction in infiltrating immune cells was accompanied by a decrease in inflammatory cytokines in the kidney (Figure 11D). Decreases in both inflammatory cytokines and infiltrating immune cells resulted in improvements in renal pathology (Figure 11F).

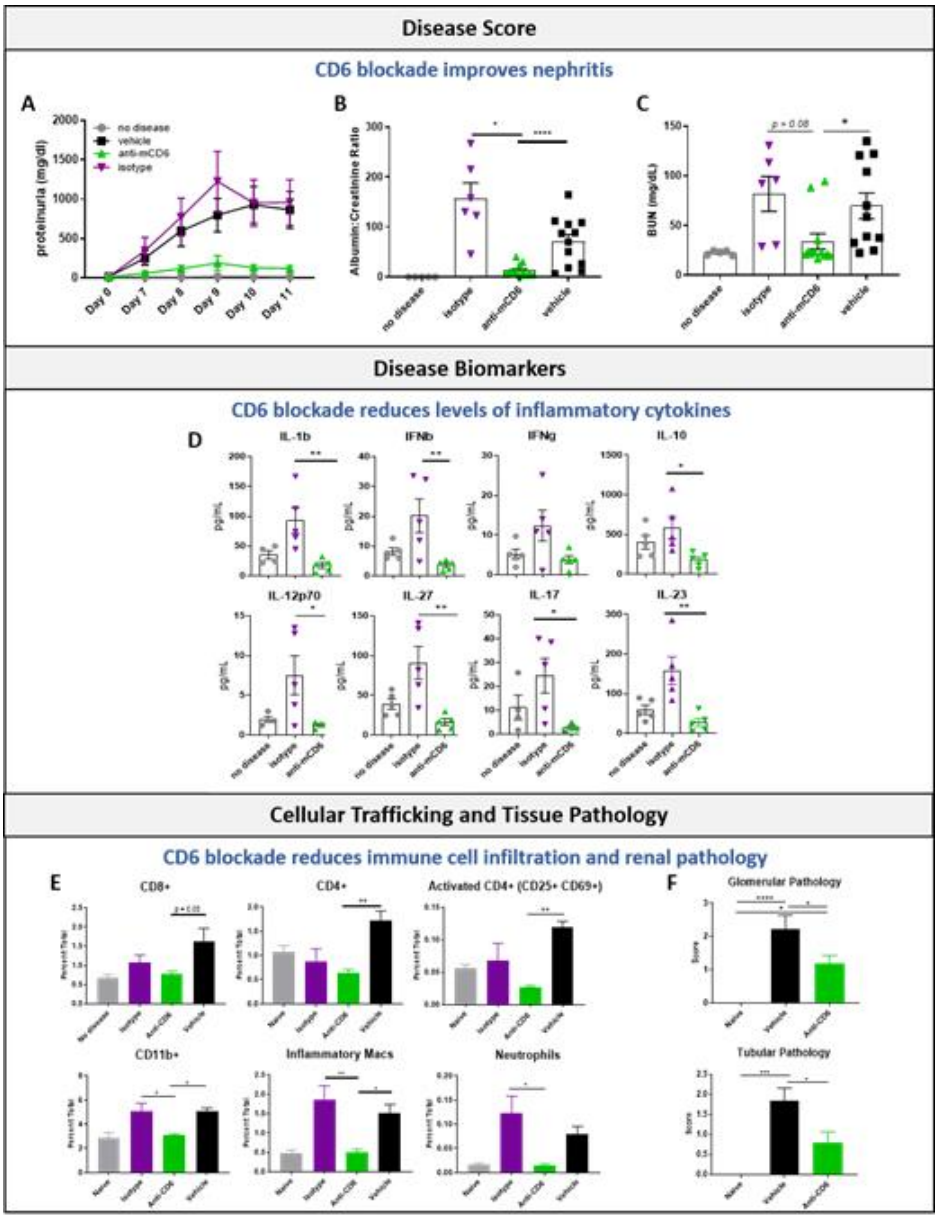


Figure 11: CD6 blockade in the murine model of glomerulonephritis inhibits disease. (A) Longitudinal proteinuria as measured by uristix. (B) urine albumin:creatinine ratio and (C) serum blood urea nitrogen levels at termination (Day 11). (D) Serum levels of inflammatory cytokines. (E) Prevalence of kidney infiltrating immune cells at termination. (F) Scoring of pathology in renal tissue collected at termination. **** $p<0.0001$; *** $p<0.001$; ** $p<0.01$; * $p<0.05$

Itolizumab: Clinically Validated in the Treatment of Immuno-Inflammatory Diseases

Itolizumab has shown activity in clinical trials in patients with rheumatoid arthritis and psoriasis. Itolizumab has been approved for the treatment of moderate to severe plaque psoriasis in India and is marketed by Biocon under the brand name ALZUMAb.

Psoriasis is a chronic immuno-inflammatory disease characterized by inflammation and aberrant hyperproliferation of keratinocytes. The pathogenesis of psoriasis is complex and numerous components of the immune system play a role, including T_h17 cells and associated cytokines, most notably IL-17.

Biocon has completed three clinical studies of ALZUMAb in India in patients with rheumatoid arthritis and chronic plaque psoriasis, with a total of 333 patients exposed to ALZUMAb at dose levels ranging from 0.2 mg/kg to 1.6 mg/kg. An overview of these clinical studies is presented in **Table 2**.

Table 2: Overview of the Biocon clinical development program of itolizumab

PHASE	STUDY NUMBER	NUMBER OF PATIENTS	DOSE LEVELS (MG/KG)	DURATION (WEEKS)	INDICATION
2	CLG007/BIO004/ RA/CD6/2006	70	0.2, 0.4, and 0.8	12	Rheumatoid arthritis
2	T1hAb-CT1-001-07	40	0.4, 0.8, and 1.6	8	Chronic plaque psoriasis
3	T1hAb-CT3-002-09 (TREAT-PLAQ)	223	0.4 and 1.6	52	Chronic plaque psoriasis

In addition to the clinical trials described above, 35 patients have received itolizumab in prior clinical trials conducted in Cuba for the treatment of rheumatoid arthritis.

The Phase 3 TREAT-PLAQ trial was a randomized, double-blind, placebo controlled, multi-arm, multi-dose, one-way crossover design studying 223 psoriasis patients. Results from this trial demonstrated that ALZUMAb had a favorable safety and tolerability profile and durable efficacy as measured by psoriasis area and severity index, or PASI. The primary end point was the proportion of patients with at least 75% improvement in PASI score, or PASI 75, at Week 12.

In Arm A patients received ALZUMAb at 0.4 mg/kg weekly for the first four weeks, then 1.6 mg/kg every two weeks until Week 12; in Arm B patients received ALZUMAb at 1.6 mg/kg every two weeks until Week 12. At Week 12 only 2.3% of patients receiving placebo achieved PASI 75 compared to 27.0% and 36.4% of patients achieving PASI 75 by Week 12 in Arms A (p value = 0.0172) and B (p value = 0.0043), respectively. At Week 12, patients in the placebo arm crossed over to treatment with ALZUMAb. Following Week 28, patients that responded to ALZUMAb (those that reached PASI 75) were re-randomized to one of two groups, either cessation of drug (n =40) or maintenance therapy (n = 39, with 1.6mg/kg of drug given every 3 months). Prior ALZUMAb treatment produced a durable effect in patients that were no longer given drug, with 53% of patients maintaining PASI 75 and 75% at PASI 50. 67% of patients that continued ALZUMAb treatment had maintained PASI 75 scores, while 85% maintained PASI 50. Histologically, skin biopsy data show that treatment with ALZUMAb statistically significantly reduces the trafficking of T cells into the dermis and this is consistent with observed reduced severity of disease and therapeutic mechanism. See **Figure 12**.

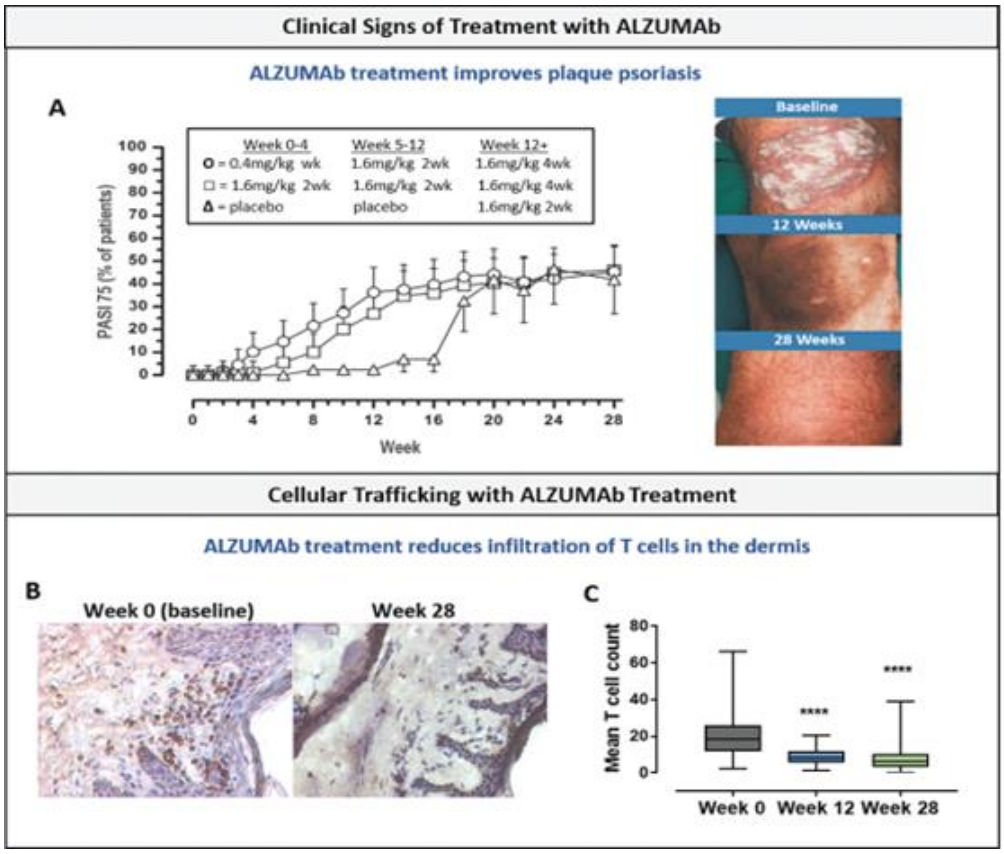


Figure 12: ALZUMAb, an approved treatment for psoriasis in India. (A) The proportion of patients who achieved a PASI 75 response at each visit until Week 28. (B) Treatment with ALZUMAb statistically significantly reduces the trafficking of T cells into the dermis. Compared to Visit 1, at Visit 16 there were statistically significantly fewer T cells in the dermis, as shown by CD3 labeling, a pan T cell marker. (C) Histogram shows the mean T cell count in the dermis was statistically significantly reduced in Week 12 and Week 28, compared to Week 0, which was consistent with the observed reduced severity of disease. ****p<0.0001.

The underlying pathophysiology of different immuno-inflammatory diseases can vary substantially, and therefore drugs that operate by different mechanisms can demonstrate diverging levels of efficacy in each condition. For example, the PASI 75 scores achieved at three months by subjects treated with ALZUMAb (36%) in its pivotal trial in psoriasis were in line with Enbrel (46-47%), an effective psoriasis drug, but they were less than the newly approved anti-IL-17 agents such as Cosentyx (66-82%). We believe the explanation for this result is that while T_h17 cells play a role in psoriasis, there are also non-T cell mediators that contribute to disease pathogenesis, suggesting that psoriasis may not be an ideal indication for this therapeutic approach. Based on published clinical trial data from multiple studies that were not conducted on a head-to-head basis, it appears that ALZUMAb has demonstrated superior PASI 75 scores in psoriasis compared to modulation of CD28 co-stimulation using Orencia (16.4%), which is approved for the treatment of psoriatic and rheumatoid arthritis. Also, a recent meta-analysis comparing efficacy across trials indicated that Orencia demonstrated superior efficacy in ACR 50 scores, a common clinical test for determining improvement in a person’s rheumatoid arthritis, than Cosentyx in certain populations of psoriatic arthritis patients. These observations illustrate the importance of matching disease pathology and therapeutic mechanism in order to optimize therapeutic benefit.

ALZUMAb was well tolerated by the patients in the Phase 3 TREAT-PLAQ trial, with infusion reactions and related events, which are expected for an antibody infusion, as the main adverse events, or AEs, attributed to ALZUMAb. The incidence of infusion reactions dropped sharply after the first few infusions. ALZUMAb did not appear to increase the rate of infections compared to placebo, and the incidence of severe adverse events, or SAEs, was low (a total of five SAEs were reported). SAEs included exfoliative dermatitis (widespread redness and peeling of the skin), erythrodermic (severe) psoriasis, infusion-related reaction, adjustment disorder with anxiety, and bacterial arthritis. No SAEs led to discontinuation or reduction of drug dosage. See **Table 3** for a summary of AEs seen during the Phase 3 trial.

Table 3. Adverse events that occurred in >5% of subjects in either ALZUMAb treatment arm, placebo arm, or overall in the trial.

Weeks 1-12	**ALZUMAb** (n = 180) n (%)	**Placebo** (n = 43) n (%)
Any Adverse Event	72 (40.0%)	20 (46.5%)
Infusion Reaction (acute)	33 (18.3%)	1 (2.3%)
Infection	6 (3.3%)	4 (9.3%)
Pruritus (itching)	5 (2.8%)	3 (7.0%)

Weeks 13-52	**ALZUMAb** (n = 223) n (%)
Any Adverse Event	111 (49.8%)
Infusion Reaction (acute)	38 (17.0%)
Pyrexia (fever)	19 (8.5%)
Infection	17 (7.6%)
Pruritus	12 (5.4%)

An examination of lymphocyte counts in the study noted a mild decrease in the mean absolute lymphocyte count, or ALC, in the two ALZUMAb treatment arms at the initiation of treatment during the placebo controlled portion of the study (weeks 1-12). The decrease that was observed tended to occur after the first dose. See **Figure 13**. These observed changes were not associated with an increase in secondary infection.

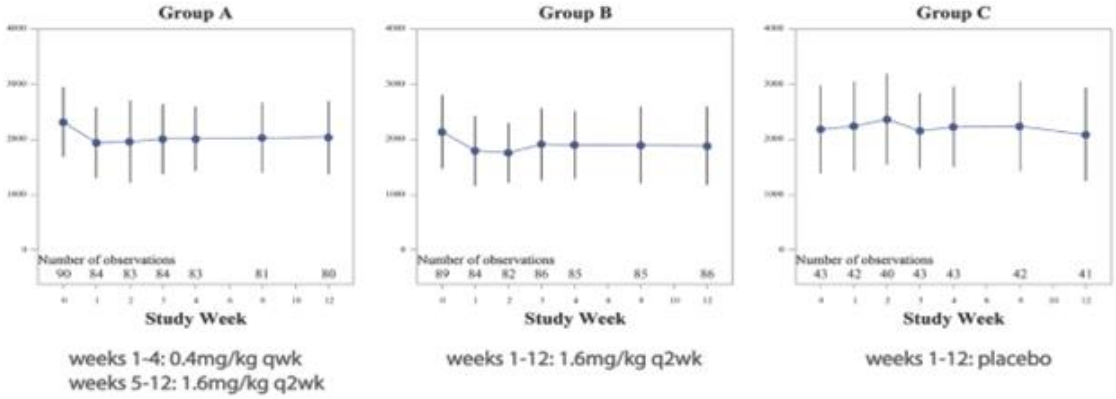
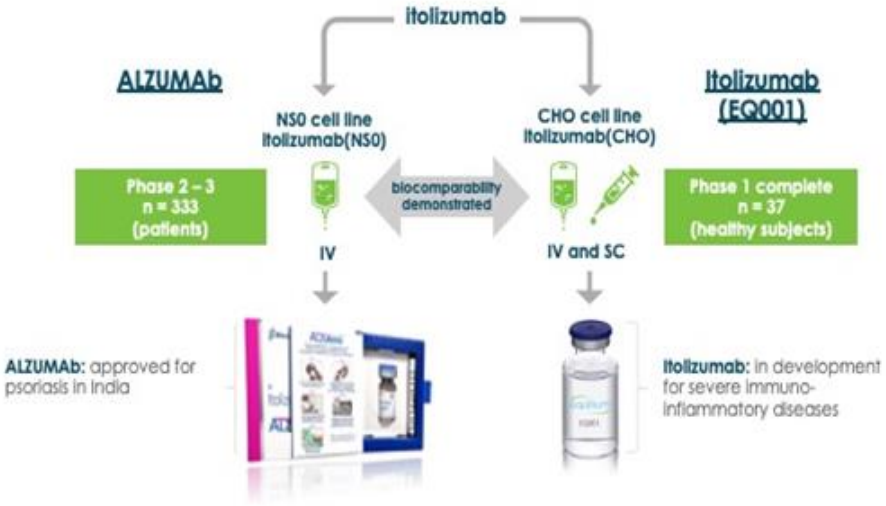


Figure 13: Lymphocyte counts in the peripheral blood of psoriasis patients during treatment with ALZUMAb. Graphs depict mean ALC (+/- standard deviation) of each treatment group during the first 12 weeks following initiation of treatment. The treatment regimen of each group is specified beneath the respective graph. Groups A and B, which received ALZUMAb, exhibited a modest decrease in ALC after the first dose but not subsequent doses.

Since approval and as of the current cut-off date of August 10, 2017 for the most recent Periodic Safety Update Report, ALZUMAb has accrued approximately 275 patient-years of use. Post-market safety surveillance has demonstrated 27 AE reports in that time period, of which four have been noted as serious, including infusion reaction, type 1 hypersensitivity, diarrhea and urticaria. The overall safety profile is favorable and has remained largely unchanged from the time of approval.

Itolizumab (EQ001) Product Development

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 is available in IV and subcutaneous injection, or SC, formulations. CHO cell lines are the industry-standard antibody therapeutic production system. Itolizumab (EQ001) is manufactured by Biocon at commercial scale in an FDA regulated manufacturing facility in India. We have two active INDs with the FDA for the use of itolizumab (EQ001) in the treatment of aGVHD and lupus nephritis. The IND submissions for these indications contained data from Biocon demonstrating analytical biocomparability of itolizumab (EQ001) 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, 1.6mg/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, here 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 was 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 itoliuzma (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 developing itolizumab (EQ001) for the treatment of uncontrolled asthma, aGVHD, and lupus nephritis. We initiated a Phase 1b proof-of-concept clinical trial in patients with uncontrolled asthma in June 2019, a Phase 1b/2 clinical trial for the treatment of aGVHD in March 2019, and a Phase 1b proof-of-concept clinical trial in patients with lupus nephritis in September 2019. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma and our Phase 1b clinical trial of itolizumab (EQ001) in 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. We are continuing to enroll 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. We continue to evaluate additional indications for future development.

Asthma Market Overview

Asthma is a heterogeneous disease characterized by different T_{eff} cell subtypes and other innate immune cells driving both allergic and autoimmune mechanisms, leading to chronic airway inflammation. Classically, asthma has been defined by two distinct immune phenotypes. There is eosinophilic asthma, characterized by high levels of eosinophils and production of immunoglobulin E, or IgE, driven predominantly by high levels of T_h2 T_{eff} cells and cytokines such as IL-4, IL-5 and IL-13, or T_h2-high. There is also non-eosinophilic asthma, characterized by low to no eosinophils and evidence suggests that other T_{eff} cells and cytokines such as T_h17 and IL-17, or non-T_h2, play a role here. While biomarkers such as fractional exhaled nitric oxide (FeNO), or blood eosinophil counts may identify allergic/eosinophilic inflammation for a subset of T_h2-high asthma patients, there is no effective biomarker for non-T_h2 asthma, which is mostly characterized by treating clinicians by the absence of the above markers. Further complicating this issue is that many patients may have the presence of both T_h2 and T_h 17 effector cells, or T_h2-low, contributing to the immunopathogenesis of their asthma. Studies have demonstrated that T_h2 and T_h17 cells are reciprocally regulated and as a result, if a drug only downregulates T_h2-mediated inflammation, then a patient may experience increased inflammation caused by T_h17 cells, and vice versa. This may explain why many patients with this disease are refractory to both steroids and the current biologics targeting eosinophils or T_h2-mediated pathways. Therefore, a therapy with a broad mechanism targeting multiple T_{eff} cell or cytokines may be required to adequately address this dynamic and heterogeneous disease.

Based on publicly available sources, we estimate that asthma impacts approximately 26 million individuals in the United States. Of these, 5–10%, or approximately 1.3–2.6 million individuals, suffer from severe disease. We estimate that 50% of the severe asthma population, or 0.6–1.3 million individuals, are uncontrolled with standard-of-care therapies such as long-acting beta-agonists and high-dose corticosteroids. We estimate that 50–60% of the uncontrolled severe asthma population fall within the non-eosinophilic T_h2-low/non-T_h2 subtype. We also estimate that 40-50% of the uncontrolled severe asthma population fall within the eosinophilic (T_h2-high) subtype; these patients may initially respond to treatment with steroids and recently approved biologic therapies which target eosinophils, IgE or T_h2-pathways.

Current therapies for uncontrolled moderate to severe or severe asthma and their limitations

Recently, several biologic therapies that specifically target IgE or T_h2-mediated cytokines have been approved by the FDA for the treatment of uncontrolled moderate to severe or severe asthma. While these therapies have been effective for certain patients with T_h2-high inflammation they have had a minimal impact in patients with T_h2-low/non-T_h2 inflammation as characterized by low levels of eosinophils, or lack thereof.

Genentech Inc.'s XOLAIR® (omalizumab), is an anti-IgE approved for the treatment of moderate to severe persistent allergic asthma that is not controlled by inhaled corticosteroids. Other recently approved biologic therapies that are directed against IL-5 or the IL-5 receptor, which together mediate eosinophil development and inflammation of the airways, include NUCALA® (mepolizumab), marketed by GlaxoSmithKline plc, CINQAIR® (reslizumab), marketed by Teva Pharmaceutical Industries Limited and FASENRA® (benralizumab), marketed by AstraZeneca plc.

In addition, Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC received approval for DUPIXENT® dupilimab, an anti-IL-4 receptor antibody, as an add-on maintenance treatment in patients with moderate to severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

Rationale for itolizumab (EQ001) for the Treatment of Uncontrolled Asthma

Itolizumab (EQ001) selectively targets both T_h2-mediated and non-T_h2-mediated inflammation in asthma pathogenesis

There remains high unmet medical need for safe, effective and targeted treatments for patients with uncontrolled asthma, especially for those with non-eosinophilic asthma for which there are currently no FDA-approved treatments. Given the limited nature of existing biomarkers coupled with the reciprocally regulated nature of the disease, we believe there remains an unmet need for a treatment that can cover the full spectrum of uncontrolled asthma patients including T_h2-high and non-T_h2 asthma.

While eosinophilic asthma is associated with Th2-mediated inflammation, non-eosinophilic asthma is associated with T_h2 and/or T_h17-mediated inflammation. Preclinical data demonstrates that modulating the CD6-ALCAM pathway can broadly inhibit the activity and trafficking of both T_h2 and T_h17 T_{eff} cells reducing levels of pathogenic cytokines such as IL-4, IL-5, IL-13 and IL-17.

We believe the unique mechanism of action of itolizumab (EQ001) can selectively target elements of the underlying pathogenesis of both eosinophilic (Th2-high) and non-eosinophilic (T_h2-low and non-T_h2) severe asthma by: a) inhibiting both T_h2 and T_h17 cell proliferation and cytokine secretion; b) inhibiting trafficking of T_h2 and T_h17 cells into lung tissues; and c) reducing the T_h2 or T_h17:T_{reg} ratios associated with severe asthma. See **Figure 14.**

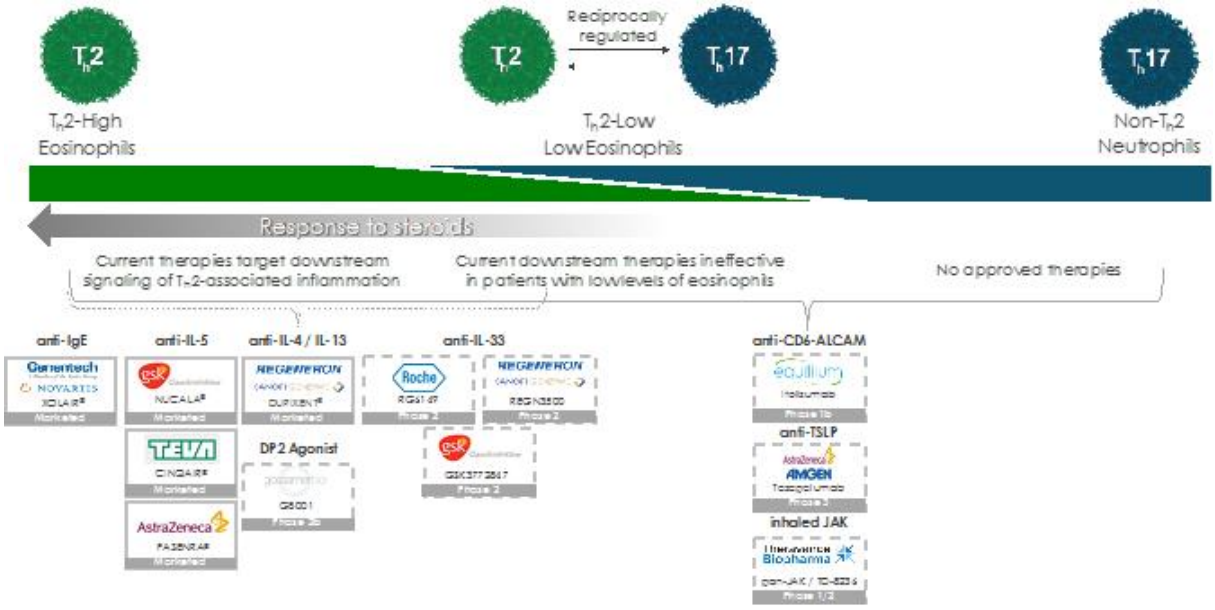


Figure 14: Th17 cells expressing CD6 drive severe refractory asthma. Current approved therapeutic approaches target downstream signaling of Th2-mediated inflammation characterized by high levels of eosinophils and are largely ineffective in patients with Th2-low or non-Th2-mediated inflammation characterized by low levels of eosinophils. We believe the upstream mechanism of itolizumab (EQ001) can uniquely address both the Th2- and Th17-mediated inflammation driving severe asthma pathogenesis.

Translational research program supporting itolizumab (EQ001) in uncontrolled asthma

To further validate the use of itolizumab (EQ001) in uncontrolled asthma, we have an ongoing translational research program assessing the role of the CD6-ALCAM pathway in severe asthma patients. Preliminary findings derived from analysis of gene expression datasets support the presence of increased levels of CD6+, CD4 T cells, and ALCAM expression in the lungs of severe asthma patients. Gene expression in cells collected from the lungs of non-asthma, steroid-sensitive moderate asthma, and steroid-insensitive severe asthma patients, suggest that CD6 is significantly elevated in severe asthma, likely due to increases in CD4 T cells as supported by higher CD4 gene expression. A subset of these CD4 T cells are believed to be T_h17 cells as the severe asthma patients also demonstrated significantly higher levels of the T_h17 cytokines such as IL-17A and IL-17F. Interestingly, the ligand of CD6, ALCAM, may also be implicated in severe asthma. Analysis of gene expression in lung tissue from a separate set of patients suggests higher expression of the ALCAM within the airway of patients who have died from asthma, establishing the presence of the necessary components of the CD6 pathway in asthmatic lungs. See **Figure 15**.

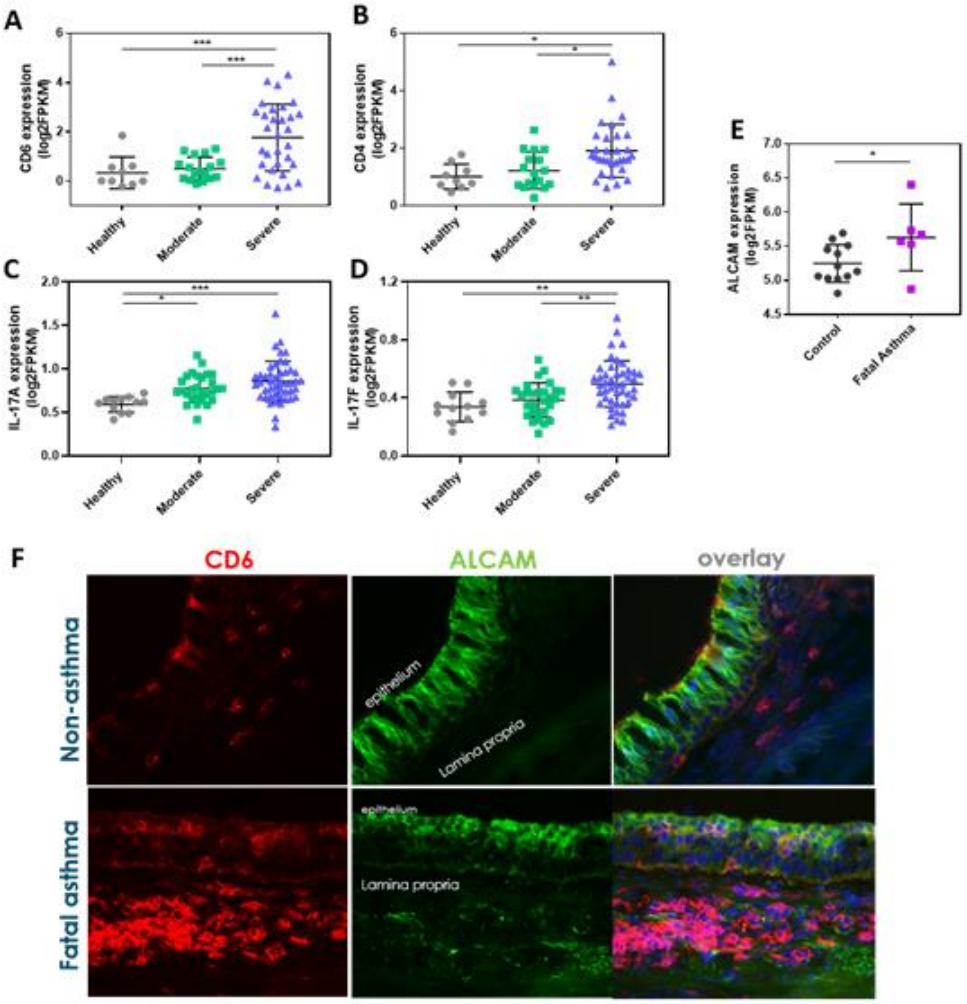


Figure 15: CD6 is upregulated in cells collected from lungs of severe asthma patients. (A thru D) Analysis of gene expression in cells collected from lungs of healthy non-asthma, moderate steroid-sensitive asthma and severe steroid-insensitive asthma patients as part of two multi-center prospective observational studies (Study of the Mechanisms of Asthma (MAST; NCT00595153); Bronchoscopic Exploratory Research Study of Biomarkers in Corticosteroid-refractory Asthma (BOBCAT) study). (A) Patients with severe asthma demonstrate higher levels of CD6 expression predominantly due to increases in CD4 T cells as supported by increased CD4 expression (B), implicating the presence of CD6+ CD4 T cells in severe asthma. (C) The severe asthma group also exhibited higher expression of Th17 cytokines IL-17A and (D) IL-17F, suggesting a subset of the CD4 T cells are Th17 cells. (E) Gene expression in smooth airway muscle from lung tissue of fatal asthmatic patients suggest elevation of the CD6 ligand ALCAM. (F) Staining of fatal asthma patient lung tissue for CD6 and ALCAM expression suggests increased numbers of CD6+ cells, upregulation of ALCAM in the lamina propria (mucosa), and co-localization of CD6+ cells with ALCAM expressing tissue. ***p<0.001, **p<0.01, *p<0.05.

Development Plan in Uncontrolled Moderate to Severe Asthma

We initiated a Phase 1b proof-of-concept multiple ascending dose clinical trial of itolizumab (EQ001) for the treatment of uncontrolled moderate to severe asthma in June 2019. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma. 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. Prior to pausing, the study was enrolling uncontrolled moderate to severe asthma patients regardless of baseline eosinophil level. Itolizumab (EQ001) is administered subcutaneously in this study and a number of dose levels are being examined using a sequential dose escalation study design. The study objectives include an assessment of safety, PK/PD markers, and a number of clinical efficacy parameters.

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, there were approximately 8,500 allo-HSCT's performed in the United States in 2018 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 2018 is up to 5,000 patients and the total prevalence of GVHD could be up to 25,000 patients. We estimate that by the year 2025, the annual incidence of aGVHD will be up to 6,000 patients and the total prevalence of GVHD could be up to 35,000 patients.

Rationale for itolizumab (EQ001) for the Treatment of GVHD

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.

Itolizumab (EQ001) selectively targets GVHD pathogenesis

There is a high unmet medical need for a safe, effective and targeted treatment in 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 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.

Development Plan in GVHD

In the first quarter of 2019, we initiated a Phase 1b/2 multicenter clinical trial that is expected to enroll approximately 84 patients in order to evaluate the safety, tolerability, PK and clinical activity of itolizumab (EQ001) in newly diagnosed aGVHD patients and expect topline data from the Phase 1b part of the trial in the second half of 2020. All patients will be administered itolizumab (EQ001) as a front-line therapy concomitant with steroid use upon first presentation of aGVHD.

The Phase 1b part of the trial is an open-label, cohort based, multiple ascending dose escalation study that is enrolling up to 24 adult patients with Grade III-IV aGVHD in successive cohorts of three to six patients treated with multiple doses of itolizumab (EQ001). The primary objective of this part of the trial is to assess the safety and tolerability of itolizumab (EQ001) and to determine the optimal dose. Secondary objectives include assessing pharmacological activity of itolizumab (EQ001). Once an optimal dose is determined, and if the observed safety, tolerability, and pharmacological activity of itolizumab (EQ001) warrants, we will commence the Phase 2 part of the trial.

The current design of the Phase 2 part of the trial will be a randomized, double-blind, placebo-controlled study that will enroll up to 60 additional patients with Grade II-IV aGVHD, randomized in a 2:1 ratio with 40 patients on active treatment of itolizumab (EQ001) and 20 patients on placebo. The primary objective of the Phase 2 part of the trial will be to assess the clinical activity of itolizumab (EQ001) and secondary objectives include further characterizing safety and tolerability. The sample size and design of this trial may be subject to change depending on what is learned from the Phase 1b clinical trial and based on additional discussions with regulatory agencies.

We have decided to take a sequential approach to developing itolizumab (EQ001) in GVHD as we contemplate expanding the program after the initial Phase 1b part of the trial in aGVHD. Learnings from the Phase 1b portion of the aGVHD trial will inform our clinical development strategy that includes a broader life-cycle approach, potentially including cGVHD, as well as the prevention of GVHD. We believe that this sequential approach enables a more efficient and optimized development program in GVHD.

Itolizumab (EQ001) has been granted Fast Track designation for the treatment of aGVHD and Orphan Drug designations for both the prevention and treatment of aGVHD by the FDA.

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 no FDA approved drugs for this condition.

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. Thus, there is 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 refractory lupus nephritis patients.

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

Itolizumab (EQ001) selectively targets T_{eff} cells which play a central role in the pathogenesis of lupus nephritis

Lupus nephritis is a devastating disease that affects roughly half of the patients with SLE; patients with lupus nephritis have a substantially increased risk for ESRD and death. 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.

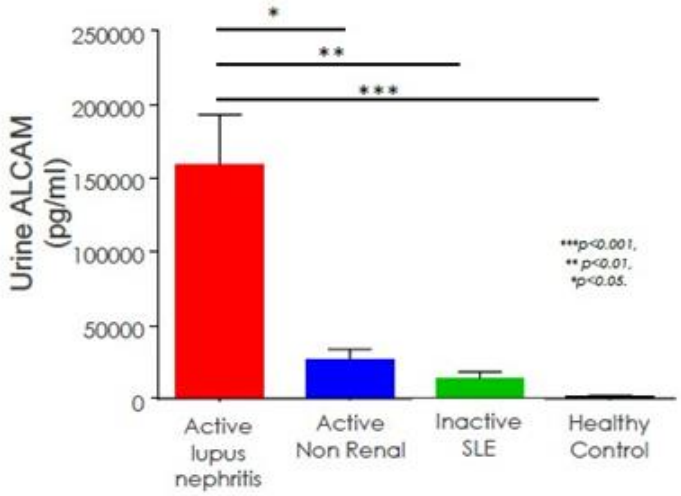
We believe the unique mechanism of action of itolizumab (EQ001) can selectively target elements of the underlying pathogenesis of lupus nephritis by: a) inhibiting multiple pathogenic T_{eff} cells and cytokine secretion; b) inhibiting trafficking of T_{eff} cells into kidney tissues; and c) reducing 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, we believe itolizumab (EQ001), which has been shown to block the CD6-ALCAM pathway and inhibits 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. An analysis of kidney biopsy specimens from patients with lupus nephritis demonstrates increased expression of CD6 on infiltrating T cells as well as high levels of expression of ALCAM on antigen presenting cells (e.g. macrophages) as well as renal resident cells across multiple compartments of the kidney.

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 16**. These data further highlight the potentially important pathogenic role of the CD6-ALCAM pathway in patients with lupus nephritis.

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).



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

Figure 16: 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.

Development Plan in Lupus Nephritis

We initiated a Phase 1b proof-of-concept multiple ascending dose escalation clinical trial in September 2019 to evaluate the safety, PK/PD, and clinical activity of itolizumab (EQ001) in lupus nephritis patients. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in 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. The study is focusing on patients with active proliferative lupus nephritis who have had an inadequate response to existing induction regiments and other therapies. In addition to evaluating the renal response to therapy, we are also capturing improvements in overall SLE disease activity across other organ systems and measuring a number of standard disease activity biomarkers in both patients with SLE without nephritis and patients with lupus nephritis . Beyond these typical measures, 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). Itolizumab (EQ001) has been granted Fast Track designation by the FDA for the treatment of lupus nephritis.

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.

Partnerships

Collaboration and License Agreement with Biocon

In May 2017, we entered into a collaboration and license agreement with Biocon, as amended in September 2018, April 2019, and December 2019, or the Biocon License, pursuant to which Biocon granted us 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. However, unless we achieve 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. We also have the right to sublicense through multiple tiers to third parties, provided such sublicenses comply with the terms of the Biocon License and we provide Biocon a copy of each sublicense agreement within 30 days of execution. If we grant a third party a sublicense of our rights to develop and commercialize Biocon Products in Australia or New Zealand, we will be required to pay Biocon a high double-digit percentage of any upfront payment we receive from such sublicensee for such sublicense, as well as a high double-digit percentage of any additional payments we receive from such sublicensee for such sublicense, including but not limited to royalty payments on net sales of Biocon Products by such sublicensee. Under the Biocon License, we granted back to Biocon a license to use our technology and know-how related to itolizumab and Biocon Products in certain countries outside of the Equillium Territory.

In consideration of 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 for up to three concurrent orphan drug clinical indications at no cost until our first U.S. regulatory approval and all other clinical drug product at cost. The Biocon Supply Agreement will remain in effect until the expiration or termination of the Biocon License.

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 initially pursue patent protection covering compositions of matter, antibody sequence diversity, epitopes, functional activity and methods of use. Throughout the development of our product candidates, we will seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use and biomarker and companion diagnostic related claims.

As of March 26, 2020, our patent portfolio related to itolizumab included patents and patent applications exclusively licensed from Biocon in the United States and Canada, as well as a pending international patent application 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 Clinical Supply Agreement with Biocon."

Specifically, as of March 26, 2020, our licensed rights from Biocon related to itolizumab included five issued patents in the United States, two issued patents in Canada, five pending patent applications in the United States, one of which is allowed, and two pending patent applications in Canada. Four 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. One of our issued U.S. patents is expected to expire in 2034 (absent any patent term extension for regulatory delays), and includes claims directed to treating multiple sclerosis with itolizumab in certain patients exhibiting increased numbers of T_h17 cells, wherein the method includes monitoring IL-23R expression. Our issued Canadian patents are expected to expire between 2027 and 2030. 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 pending PCT patent application related to methods of using itolizumab to treat severe asthma. If granted, this patent is expected to expire in 2039, 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 152 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 Our 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.

Specifically, there are several companies developing or marketing treatments that may be approved for the same indications and/or diseases as our lead product candidate itolizumab (EQ001).

Asthma

Several biologic therapies that specifically target IgE or T_h2-mediated cytokines have been approved by the FDA for the treatment of asthma including products developed by AstraZeneca plc, GlaxoSmithKline plc, Sanofi-Genzyme, Novartis AG, Regeneron Pharmaceuticals, Inc., Roche Holding AG and Teva Pharmaceutical Industries Limited.

In addition, Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC have received approval for dupilimab, an anti-IL-4 receptor antibody, as an add-on maintenance treatment in patients with moderate to severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

We are also aware of several companies with development programs in this indication, including Amgen Inc., AnaptysBio, Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, GlaxoSmithKline plc, Gossamer Bio, Inc., Regeneron Pharmaceuticals, Inc., Roche Holding AG, Sanofi-Aventis U.S. LLC. and Theravance Biopharma, Inc.

aGVHD

Corticosteroids, or steroids, remain the first-line of therapy for aGVHD. There are currently no FDA-approved therapies for the frontline 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 aGVHD, including Alpine Immune Sciences, Inc., Bristol-Myers Squibb Company, CSL Behring LLC, Fate Therapeutics, Inc., Incyte Corporation, Takeda Pharmaceutical Company Limited, Jazz Pharmaceuticals plc, Kalytera Therapeutics, Inc., Kamada Ltd., Mesoblast Limited, 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 no approved therapies for the treatment of lupus nephritis.

We are aware of several companies with development programs targeting lupus nephritis including Alexion Pharmaceuticals, Inc, Apellis Pharmaceuticals, Inc., AstraZeneca plc, Aurinia Pharmaceuticals Inc., Boehringer Ingelheim GmbH, Genentech Inc., Novartis AG, GlaxoSmithKline plc, Kezar Life Sciences, Inc. and Omeros Corporation.

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) 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 third-party 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 its FDA regulated facility in Bangalore, India.

With respect to any future product candidates, we expect to rely on third-party 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 ACA, 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.

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.

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.

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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or 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 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, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals as well as 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 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 new 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 new 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 remain legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two 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, effective January 1, 2019, as part of the Tax Cuts and Jobs Act of 2017, or Tax Act. 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 eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

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 due to subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2029 unless additional Congressional action is taken. 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 and enacted federal and state 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, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning on January 1, 2020. The final rule codified a CMS policy change that was effective January 1, 2019. While some proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative

measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control biopharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

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

Government Regulations Related to Economic Sanctions

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

One such set of regulations is the Cuban Assets Control Regulations, or CACR. The CACR prohibits U.S. persons from engaging in virtually all transactions involving property of the government of Cuba or Cuban nationals, or property in which the government of Cuba or any Cuban national has at any time on or since July 8, 1963 had any interest of any nature whatsoever, direct or indirect. Where activity is prohibited by the CACR, engagement in such activity must be authorized by a general or specific license granted by OFAC. The antibody sequence for both itolizumab (EQ001) and ALZUMAb was developed exclusively by Cuban nationals. We currently rely on a general license in the CACR, relating to Cuban-origin pharmaceuticals, to import and conduct clinical 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, 2019, we employed 16 employees, all of whom are full-time and engaged in research and development activities, operations, finance, business development and administration.

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. 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.

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 in this section as well as those discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes 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 Business and to the Development and Regulatory Approval of Itolizumab (EQ001)

The novel coronavirus global pandemic could adversely impact our business, including our clinical trials, our supply chain and our business development activities.

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 may be affected by the coronavirus. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the coronavirus. Current or potential 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 to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. In March 2020, as a result of impacts and risks associated with the coronavirus, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma and our Phase 1b clinical trial of itolizumab (EQ001) in 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. We are continuing to enroll 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. 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.

The coronavirus continues to rapidly evolve. The extent to which the coronavirus 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.

We have a very limited operating history and have never generated any revenues.

We are an early-stage biotechnology company with a very limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. We were 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 two initial INDs and commencing clinical development of itolizumab (EQ001). We have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, 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 longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

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, 2019 and 2018, our net losses were $25.6 million and $13.3 million, respectively. As of December 31, 2019, we had an accumulated deficit of $41.1 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, including the ongoing and planned 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. In addition, if we obtain regulatory approval for itolizumab (EQ001), we expect to incur increased sales and marketing expenses. 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 are highly dependent on the success of our product candidate, itolizumab (EQ001), which is in early stage 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 uncontrolled asthma, aGVHD and lupus nephritis, which may never occur. We have no product candidates in our pipeline other than itolizumab (EQ001). 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.

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 both itolizumab (EQ001) and ALZUMAb 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 planned 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.

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 will require substantial additional funding to complete the development and any commercialization of itolizumab (EQ001). 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 itolizumab (EQ001) enters and advances through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory and quality capabilities. In addition, if we obtain marketing approval for itolizumab (EQ001), we expect to incur significant commercialization expenses for marketing, sales, manufacturing and distribution.

As of December 31, 2019, we had $53.1 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, 2019 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 planned clinical trials for 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, 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 planned clinical trials for itolizumab (EQ001);
- 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 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, providing for up to $20.0 million in term loans. We borrowed $10.0 million upon execution of the Loan Agreement. Other than our term loan facility, we do not have any committed external source of funds.

In November 2019, we entered into an Open Market Sales Agreement℠ with Jefferies LLC, or Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $8.45 million from time to time through Jefferies acting as our sales agent, or ATM facility. As of December 31, 2019, we have sold an aggregate of 18,250 shares of our common stock under the ATM facility for gross proceeds of $0.1 million.

Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for sale for at least the next several years, 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. Subject to limited exceptions, our Loan Agreement also prohibits us from incurring indebtedness without the prior written consent of the lenders. 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.

We are very early in our development efforts. We only recently initiated our initial clinical trials of itolizumab (EQ001), and as a company, we have limited experience in these areas.

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 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma and our Phase 1b clinical trial of itolizumab (EQ001) in lupus nephritis. We have two active INDs with the FDA for the use of itolizumab (EQ001) in the treatment of aGVHD and lupus nephritis and we have not yet 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 planned 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 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 planned clinical trials and preclinical studies with favorable results;
- 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 third-party manufacturer, 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.

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. 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.

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.

Biocon and its partner, over which we have no control, have the rights to develop and commercialize itolizumab in geographies outside of the United States, Canada, Australia, and New Zealand. Itolizumab is approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon as ALZUMAb. In addition, a conditional approval for itolizumab was granted to Centro de Immunologia Molecular, Cuba in May 2014. This approval is subject to completion of a Phase 3 clinical trial in Cuban patients. Two clinical trials are currently open in Cuba. If serious adverse events occur with patients using ALZUMAb or during any clinical trials of itolizumab conducted by Biocon or third parties, the FDA may delay, limit or deny approval of itolizumab or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for itolizumab and a new and serious safety issue is identified in connection with use of ALZUMAb or in clinical trials of itolizumab conducted by Biocon or third parties, the FDA 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.

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.

If we experience delays in obtaining approval or if we fail to obtain approval of itolizumab, 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 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 itolizumab (EQ001) in any distinct indication, we must submit the results of preclinical studies to the FDA along with other information, including information about itolizumab (EQ001) chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of itolizumab (EQ001) in any indication, we must conduct extensive clinical studies to demonstrate the safety and efficacy of itolizumab (EQ001). 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 third parties for regulatory submissions for itolizumab (EQ001). While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third 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. To date, we have only submitted INDs for clinical trials of itolizumab (EQ001) for the treatment of aGVHD and lupus nephritis, and we will need to submit an IND for acceptance by the FDA prior to initiating any clinical trials in the United States in other indications.

The FDA may require us to conduct additional preclinical studies for itolizumab (EQ001) or any future product candidate 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 planned trials will be completed on schedule, if at all, or whether our planned 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;
- 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;
- 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;
- 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 third-party 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
- third-party 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 planned 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. One of the indications that we are pursuing, aGVHD, is an acute and life-threatening condition which may make it difficult to enroll patients in clinical trials. Enrollment in the Phase 1b portion of our aGVHD clinical trial has been progressing slower than expected due to longer site activation timelines at academic centers, a smaller number of available severe aGVHD patients as defined by Grade III-IV aGVHD, which constitutes a smaller portion of the overall aGVHD population, and higher screen failure rates due to comorbid conditions in this severe aGVHD population. 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, 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 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.

Adverse side effects or other safety risks associated with itolizumab 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 itolizumab in our ongoing and planned clinical trials. In the Phase 1 clinical trial of itolizumab (EQ001) conducted by Biocon in Australia in healthy subjects, there were no serious adverse events, dose limiting toxicities, or study drug discontinuations reported.

Biocon has completed three clinical studies of ALZUMAb in India in patients with rheumatoid arthritis and chronic plaque psoriasis, with a total of 333 patients exposed to ALZUMAb to date at dose levels ranging from 0.2 mg/kg to 1.6 mg/kg. An additional 35 patients have received itolizumab in clinical trials conducted in Cuba. In Biocon's Phase 3 clinical trial, infusion-related reactions and related events were the main adverse events attributed to itolizumab. There were five serious adverse events reported including exfoliative dermatitis (widespread redness and peeling of the skin), erythrodermic (severe) psoriasis, infusion-related reaction, adjustment disorder with anxiety, and bacterial arthritis. Since the December 27, 2012 date of authorization in India through November 30, 2019, ALZUMAb has accrued approximately 187 patient-years of use. Post-market safety surveillance has collected a total of 35 adverse events in 24 adverse event reports in that time period, of which four have been noted as serious, including infusion reaction, type 1 hypersensitivity, diarrhea and urticaria (hives). The majority of reactions have involved the dermatologic system organ class and include rash, acne, urticaria, increased pruritus (itching) and increased psoriasis. 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).

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 itolizumab (EQ001) 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 aGVHD clinical trial will die from aGVHD, 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 itolizumab (EQ001) 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 itolizumab (EQ001). Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if itolizumab (EQ001) is associated with undesirable side effects in clinical trials or has characteristics that are unexpected, we may elect to abandon or limit its 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 itolizumab (EQ001), if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many biologics 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 itolizumab (EQ001) in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of itolizumab (EQ001) 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 itolizumab (EQ001) receives marketing approval, and we or others later identify undesirable side effects caused by itolizumab (EQ001), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of itolizumab (EQ001);
- we may be required to recall a product or change the way itolizumab (EQ001) 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;
- itolizumab (EQ001) could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of itolizumab (EQ001), 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.

A Phase 1 single ascending dose clinical trial of itolizumab (EQ001) in normally healthy volunteers was conducted by Biocon in Australia, we have initiated a Phase 1b proof-of-concept clinical trial of itolizumab (EQ001) in uncontrolled moderate to severe asthma patients in Australia and New Zealand, and we may conduct additional clinical trials of itolizumab (EQ001) outside of the United States. However, 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 the occurrence of transient lymphopenia in the healthy subjects. 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.

In June 2019, we initiated a Phase 1b, multiple ascending dose escalation, proof-of-concept clinical trial of itolizumab (EQ001) in uncontrolled moderate to severe asthma in Australia and have initiated sites in Australia and New Zealand. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma. 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 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.

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 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. 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. 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 third-party 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. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA 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 itolizumab (EQ001) receives marketing approval in any indication, it 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) 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 itolizumab (EQ001) does 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 of itolizumab (EQ001), 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 itolizumab (EQ001) 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 of itolizumab (EQ001) as well as competitive biopharmaceutical products;
- the effectiveness of our or any of our potential future sales and marketing strategies;
- unfavorable publicity relating to itolizumab (EQ001);
- 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 third parties to market and sell itolizumab (EQ001), 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 itolizumab (EQ001) 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) 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 third parties for these functions than if we were to market, sell and distribute itolizumab (EQ001) ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market itolizumab (EQ001) 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 itolizumab (EQ001); 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.

Other products in the same class as itolizumab have already been approved or are further along in development. We are aware of both private and public companies with development programs in aGVHD, including Alpine Immune Sciences, Inc., Bristol-Myers Squibb Company, CSL Behring LLC, Fate Therapeutics, Inc., Incyte Corporation, Takeda Pharmaceutical Company Limited, Jazz Pharmaceuticals plc, Kalytera Therapeutics, Inc., Kamada Ltd., Mesoblast Limited, and Xenikos B.V. Major, currently marketed asthma therapies include several biologic therapies that specifically target IgE or T_h 2-mediated cytokines including products developed by AstraZeneca plc, GlaxoSmithKline plc, Sanofi-Genzyme, Novartis AG, Regeneron Pharmaceuticals, Inc., Roche Holding AG and Teva Pharmaceutical Industries Limited. In addition, Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC have received approval for dupilimab, an anti-IL-4 receptor antibody, as an add-on maintenance treatment in patients with moderate to severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. We are aware of several companies with development programs in moderate to severe asthma, including Amgen Inc., AnaptysBio, Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, GlaxoSmithKline plc, Gossamer Bio, Inc., Regeneron Pharmaceuticals, Inc., Roche Holding AG, Sanofi-Aventis U.S. LLC. and Theravance Biopharma, Inc. We are also aware of several companies with development programs targeting lupus nephritis including Alexion Pharmaceuticals, Inc, Apellis Pharmaceuticals, Inc., AstraZeneca plc, Aurinia Pharmaceuticals Inc., Boehringer Ingelheim GmbH, Genentech Inc., Novartis AG, GlaxoSmithKline plc, Kezar Life Sciences, Inc., and Omeros Corporation.

Many of our competitors, such as large pharmaceutical and biotechnology companies like Amgen Inc. and Bristol-Myers Squibb Company have longer operating histories and 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 do. 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 Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical 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 revenue may be adversely affected and our business may suffer.

We only have the rights to itolizumab (EQ001) for the United States, Canada, Australia and New Zealand, 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 uncontrolled moderate to severe asthma, aGVHD and lupus nephritis. Our projections of addressable patient populations in the United States, Canada, Australia and New Zealand 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.

Risks Related to Manufacturing and Our Reliance on Third Parties

The manufacture of biologics is complex and Biocon, our third-party manufacturer, may encounter difficulties in production, distribution and delivery of such biologics. 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 manufacture 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. 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 third parties 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 planned 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.

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.

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.

Our reliance on third 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 third parties to research and develop and to manufacture itolizumab (EQ001), we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, 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 these 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.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements 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 with third parties, independent development or publication of information by any of our third-party 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 third parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for 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 third party. 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, 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, that 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 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. 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 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 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 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 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 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 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 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 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, 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.

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.

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 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 Employee Matters and Managing Growth and Other Risks Related to Our Business

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, Stephen Connelly, Ph.D., who serves as our Chief Scientific Officer, and Krishna R. Polu, M.D., who serves as our Executive Vice President Research & Development and Chief Medical 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, 2019, we had 16 full-time employees. As we advance itolizumab (EQ001) in clinical development, 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 receives 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) 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 third party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our ongoing and planned clinical trials and the manufacture of itolizumab (EQ001) and any future product candidates. We cannot assure you that the services of such third party contract organizations, 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.

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 third-party 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.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of itolizumab (EQ001) or any future product candidates could be delayed.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of itolizumab (EQ001) or any future product candidates could be delayed. In addition, the loss of clinical trial data for itolizumab (EQ001) or any future product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). 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.

As of May 25, 2018, the General Data Protection Regulation, or GDPR, has replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes several stringent requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third party processors in connection with the processing of the personal data. The GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs could increase, and harm our business and financial condition. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the European Union member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. To comply with the new data protection rules imposed by GDPR we may be required to put in place additional mechanisms ensuring compliance. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

European data protection law also imposes strict rules on the transfer of personal data out of the European Union, including to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this Framework is under review and there is currently litigation challenging other European Union mechanisms for adequate data transfers (i.e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our European Union business to the United States, and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

Further, the United Kingdom's withdrawal from the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide new disclosures to California consumers, and provides such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Compliance with U.S and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We or the third 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 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 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, or the Code. The Tax Cuts and Jobs Act, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, repeal of the alternative minimum tax for corporations, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income, elimination of carrybacks of net operating losses arising in taxable years ending after December 31, 2017, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings

(subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. We do not expect the Tax Cuts and Jobs 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 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.

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

As of December 31, 2019, we had aggregate U.S. federal net operating loss, or NOL, carryforwards of approximately $28.3 million. Our federal NOLs generated in taxable years ending prior to 2018 could expire unused. Under the Tax Cuts and Jobs Act, federal NOLs incurred in taxable years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is generally limited to 80% of future taxable income. In addition, under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income 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, if we earn net taxable income, our ability to use our pre-ownership change NOL carryforwards to offset U.S. federal taxable income 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.

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

In September 2019, we entered into the Loan Agreement with Oxford Finance LLC and Silicon Valley Bank 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 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.

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 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, 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 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 new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and 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 a new 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 manufacturer's outpatient drugs to be covered under Medicare Part D; (vi) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (vii) 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; (viii) created a licensure framework for follow-on biologic products; and (ix) 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 remain 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 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." Since the enactment of the Tax Cuts and Jobs Act, there have been additional amendments to certain provisions of the Affordable Care Act, and we expect the current Trump administration and Congress will likely continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the Affordable Care Act. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its

entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

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 2029, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted state and federal legislation 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, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and to increase patient access to lower-cost generic and biosimilar drugs. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. While some of the existing measures and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states in the United States have increasingly passed legislation and implemented 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. 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.

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 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, 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 third parties 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.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the other rules and regulations of the SEC, or any securities exchange relating to public companies. The Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley, as well as rules subsequently adopted by the SEC, and The Nasdaq Global Market to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. 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. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

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 third parties 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. 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. 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 no 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.

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.

Risks Related to 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 subjects in our ongoing and planned clinical trials;
- results from our ongoing and planned clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- 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;
- 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 or by our competitors;
- 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 majority 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 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 November 2019, we entered into the ATM facility with Jefferies under which we may offer and sell shares of our common stock having an aggregate offering price of up to $8.45 million from time to time through Jefferies acting as our sales agent. As of December 31, 2019, we have sold an aggregate of 18,250 shares of our common stock under the ATM facility for gross proceeds of $0.1 million. 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 23, 2020, we had 17,618,591 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.

We will have broad discretion in the use of working capital and may not use it effectively or in ways that increase the value of our share price.

We cannot specify with any certainty the particular uses of working capital, but we currently expect such uses will include funding research and development of itolizumab (EQ001) and general corporate purposes as well as potentially acquiring additional products. We will have broad discretion in the application of working capital, and you and other stockholders may disagree with how we spend or invest the working capital. The failure by our management to apply our working capital effectively could adversely affect our business and financial condition. Pending their use, we may invest working capital in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

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.

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 (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 choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction).

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 is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the

federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of 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 and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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 2022. We also lease approximately 2,050 square feet of space for general office purposes located in South San Francisco, California under a lease that expires in February 2021.

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 23, 2020, there were approximately 45 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 regarding securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information under the heading "Securities Authorized for Issuance under Equity Compensation Plans" in Item 11 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On October 11, 2018, our Registration Statement on Form S-1 (file No. 333-227387) was declared effective by the SEC for our initial public offering of common stock, or IPO. On October 16, 2018, we sold an aggregate of 4,670,000 shares of common stock and on November 2, 2018, we sold an additional 445,097 shares of common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, each at an offering price of $14.00 per share, for aggregate gross proceeds of approximately $71.6 million. After deducting underwriting discounts, commissions and offering costs incurred by us of approximately $7.1 million, the net proceeds from the offering were approximately $64.5 million. The joint book-running managers for the offering were Jefferies LLC, Leerink Partners LLC and Stifel, Nicolaus & Company, Incorporated. No offering costs were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC on October 12, 2018. Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents and short-term investments. As of December 31, 2019, we have used $21.1 million of the net proceeds from the IPO. Pending such uses, we plan to continue investing the unused proceeds from the IPO in fixed, non-speculative income instruments and money market funds.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data.

Not required for smaller reporting companies.

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 deep understanding of immunobiology to develop products 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. Activated T_{eff} cells drive a number of immuno-inflammatory diseases across therapeutic areas including transplant science, systemic autoimmunity, pulmonary, neurologic, gastrointestinal, renal, vascular, ophthalmic and dermatologic disorders. Therefore, we believe itolizumab (EQ001) may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.

Our pipeline is focused on developing itolizumab (EQ001) as a potential best-in-class, disease modifying treatment for multiple severe immuno-inflammatory disorders. Our Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, for acute graft-versus-host disease, or 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 a Phase 1b/2 clinical trial of itolizumab (EQ001) for the treatment of aGVHD. In June 2019, we initiated a Phase 1b proof-of-concept clinical trial in Australia for the treatment of uncontrolled moderate to severe asthma. Our IND for lupus nephritis was accepted by the FDA in July 2019, and we initiated a Phase 1b proof-of-concept clinical trial for the treatment of lupus nephritis in September 2019. The FDA granted itolizumab (EQ001) Fast Track designation for the treatment of lupus nephritis in December 2019. In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, we decided to pause enrollment of our Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma and our Phase 1b clinical trial of itolizumab (EQ001) in 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. We are continuing to enroll 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.

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. Our selection of current and future indications is driven by our analysis of the scientific, translational, clinical and commercial rationale for advancing itolizumab (EQ001) into further development.

We acquired rights to itolizumab (EQ001) for the territories of the United States and Canada in May 2017 pursuant to a collaboration and license agreement with Biocon, and the territories of Australia and New Zealand in December 2019, pursuant to an amendment to that agreement. Following completion of a Phase 3 clinical trial conducted by Biocon outside of North America, itolizumab (EQ001) was approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon in India as ALZUMAb. Today, India is the only jurisdiction where ALZUMAb is approved or marketed. Our partnership 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 FDA. 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.

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 preclinical research, filing two initial INDs and commencing clinical development of itolizumab (EQ001). 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, private placements of convertible promissory notes, term loans and our ATM facility. We have incurred losses since our inception. Our net losses were $25.6 million and $13.3 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $41.1 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development activities, preclinical 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 continue our research and development activities, including the ongoing and planned 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, and incur general corporate costs. We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2019, 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 will not be for at least the next several years, 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. 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. 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.

ATM Facility

In November 2019, we entered into the ATM facility with Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $8.45 million from time to time through Jefferies acting as our sales agent. Sales of our shares of common stock will be made by any method that is deemed to be an “at the market offering”. As of December 31, 2019, we sold 18,250 shares of our common stock under the ATM facility for gross proceeds of $0.1 million.

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 we do not expect to occur for at least the next several years, 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 research and development activities, preclinical activities, 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 and preclinical activities on our behalf;
- costs related to preparing and filing two INDs with the FDA; and
- costs related to general overhead expenses such as travel, insurance and rent expenses 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 preclinical and clinical development.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of itolizumab (EQ001) and potentially expand the number of indications for which we are developing itolizumab (EQ001). The successful development of itolizumab (EQ001) is highly uncertain. At this time, due to the inherently unpredictable nature of preclinical and clinical development, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of itolizumab (EQ001) or the period, if any, in which material net cash inflows from itolizumab (EQ001) 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:

- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites 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, finance, and accounting functions. Other significant costs include legal fees relating to patent and corporate matters, insurance, travel and facility costs.

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 to commercialize such product. However, we do not expect to receive any such regulatory approval for at least the next several years, if ever.

Interest Expense

Interest expense consists of interest on our term loans payable and convertible promissory notes, which convertible promissory notes were converted into shares of common stock in connection with our IPO in October 2018.

Interest Income

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

Other Income, net

Other income, net consists of net foreign currency transaction gains related to our Australian subsidiary.

Change in Fair Value of Biocon Anti-Dilution Right

Prior to the IPO, we were required to issue to Biocon additional shares of common stock to maintain Biocon's ownership interest of our fully-diluted capitalization until we have received aggregate cumulative gross proceeds from sales of equity securities of $15.0 million, or the Biocon Anti-Dilution Right. The Biocon Anti-Dilution Right was classified as a liability in the accompanying consolidated balance sheet. The Biocon Anti-Dilution Right was recorded at fair value using the precedent transaction method. The fair value of the Biocon Anti-Dilution Right was re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense). The Biocon Anti-Dilution Right was satisfied in full upon the issuance of 228,060 shares of common stock to Biocon in connection with the completion of the IPO.

Results of Operations

Comparison of the Year Ended December 31, 2019 and 2018

The following table sets forth our results of operations for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2018	Increase
Research and development	$ 17,640	$ 4,943	$ 12,697
General and administrative	9,087	3,672	5,415
Interest expense	(279)	(2,558)	2,279
Interest income	1,391	340	1,051
Other income, net	15	-	15
Change in fair value of Biocon Anti-Dilution Right	-	(2,417)	2,417

Research and Development Expenses

Research and development expenses were $17.6 million for the year ended December 31, 2019, compared to $4.9 million for the year ended December 31, 2018. The increase in research and development expense primarily includes the following changes:

- $7.4 million increase in clinical development activities
- $3.9 million increase in employee compensation and benefits and consulting expenses
- $0.7 million increase in preclinical research activities
- $0.7 million increase in overhead expenses primarily related to increased travel costs associated with our research and development activities

General and Administrative Expenses

General and administrative expenses were $9.1 million for the year ended December 31, 2019, compared to $3.7 million for the year ended December 31, 2018. The increase in general and administrative expense primarily includes the following changes:

- $2.9 million increase in employee compensation and benefits and consulting expenses
- $1.8 million increase in costs associated with being a public company
- $0.7 million increase related to legal and audit fees

Interest Expense

Interest expense was $0.3 million for the year ended December 31, 2019, compared to $2.6 million for the year ended December 31, 2018. The decrease in interest expense consists primarily of non-cash interest expense incurred in 2018, including accretion of debt premium and issuance costs in relation to our convertible promissory notes. The convertible promissory notes were converted into equity in connection with the IPO in October 2018. In 2019, interest expense incurred was primarily associated with our term notes payable.

Interest Income

Interest income was $1.4 million for the year ended December 31, 2019, as compared to $0.3 million for the year ended December 31, 2018. The increase in interest income was primarily due to higher average cash, cash equivalents and short-term investment balances during 2019 compared to 2018.

Other Income, net

Other income, net consists of net foreign currency transaction gains related to our Australian subsidiary.

Change in Fair Value of Biocon Anti-Dilution Right

Change in fair value of the Biocon Anti-Dilution Right was $2.4 million for the year ended December 31, 2018. In connection with our IPO in October 2018, the liability associated with the Biocon Anti-Dilution Right was reclassified to stockholders' equity. Therefore, there was no further activity in the year ended December 31, 2019.

Liquidity and Capital Resources

Sources of Liquidity

From inception through December 31, 2019, we have raised an aggregate of approximately $91.1 million in gross proceeds pursuant to our IPO, private placements of convertible promissory notes, proceeds from our term loans and proceeds from equity issuances under our ATM facility.

In September 2019, we entered into the Loan Agreement 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 Term A Loan. Under the terms of the Loan Agreement, we may, at our sole discretion, borrow from the Lenders (i) up to an additional $5.0 million, or Term B Loan, upon our achievement of positive topline data in either our (a) itolizumab (EQ001) Phase 1b aGVHD trial or (b) itolizumab (EQ001) Phase 1b asthma trial, supporting a formal decision to advance into Phase 2 development, and as confirmed by our Board of Directors, or the Term B Milestone, and (ii) up to an additional $5.0 million, or Term C Loan and together with Term A Loan and Term B Loan, the Term Loans, upon our achievement of positive topline data in both our EQ001 Phase 1b aGVHD trial and our itolizumab (EQ001) Phase 1b asthma trial, supporting a formal decision to advance into Phase 2 development, and as confirmed by our Board of Directors, or the Term C Milestone. We may draw the Term B Loan during the period commencing on the date of the occurrence of the Term B Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term B Milestone, and (iii) the occurrence of an event of default and may draw the Term C Loan during the period commencing on the date of the occurrence of the Term C Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term C Milestone, and (iii) the occurrence of an event of default.

In November 2019, we entered into the ATM facility with Jefferies under which we may offer and sell shares of our common stock having an aggregate offering price of up to $8.45 million from time to time through Jefferies acting as our sales agent. As of December 31, 2019, we have sold an aggregate of 18,250 shares of our common stock under the ATM facility for gross proceeds of $0.1 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance and expand our clinical development of itolizumab (EQ001). 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, and general overhead costs.

We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2019, 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 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 planned clinical trials for itolizumab (EQ001);
- the number and scope of indications we decide to pursue for itolizumab (EQ001) development;
- the cost, timing and outcome of regulatory review of any Biologics License Application, or 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.

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. 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 $41.1 million as of December 31, 2019. 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).

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, 2019	Year Ended December 31, 2018
Net cash (used in) provided by:		
Operating activities	$ (22,949)	$ (7,526)
Investing activities	(2,166)	(37,434)
Financing activities	9,836	66,365
Effect of exchange rate changes on cash	(10)	-
Net (decrease) increase in cash and cash equivalents	$ (15,289)	$ 21,405

Operating Activities

Net cash used in operating activities during the year ended December 31, 2019 primarily consisted of net loss of $25.6 million plus net non-cash adjustments of $2.0 million and net changes in operating assets and liabilities of $0.7 million. The primary non-cash adjustments to net loss include stock-based compensation of $2.3 million and non-cash interest expense of $0.1 million offset by accretion of discount on investments of $0.4 million. Cash flow impacts from changes in operating assets and liabilities were primarily driven by increases in accounts payable and accrued expenses of $1.8 million associated with higher clinical costs to support our clinical trials as well as higher bonus compensation accruals offset by $1.1 million of increased prepayments related to clinical costs and director and officer insurance premiums.

Net cash used in operating activities during the year ended December 31, 2018 primarily consisted of net loss of $13.3 million plus net non-cash adjustments of $5.4 million and net changes in operating assets and liabilities of $0.3 million. The primary non-cash adjustments to net loss include non-cash interest expense of $2.6 million, $2.4 million for the change in fair value of the Biocon Anti-Dilution Right and stock-based compensation of $0.4 million. Cash flow impact from changes in operating assets and liabilities were primarily driven by increases in accounts payable and accrued expenses of $1.4 million offset by prepaid expenses of $1.1 million primarily related to payments in the fourth quarter of 2018 for our director and officer insurance premiums.

Investing Activities

Net cash used in investing activities totaled $2.2 million during the year ended December 31, 2019. We purchased $54.6 million of short-term investments and $52.5 million of our short-term investments matured during the period. Purchases of property and equipment for the year ended December 31, 2019 totaled $0.1 million.

Net cash used in investing activities was $37.4 million during the year ended December 31, 2018 primarily due to purchases of short-term investments during the period.

Financing Activities

Net cash provided by financing activities totaled $9.8 million during the year ended December 31, 2019. We received net proceeds from the issuance of term notes payable totaling $9.9 million and proceeds from both the exercise of stock options and the sale of shares under our employee stock purchase plan totaling $0.1 million offset by a net use of cash of $0.2 million related to the ATM facility costs offset by the sale of shares under the ATM facility.

Net cash provided by financing activities totaled $66.4 million during the year ended December 31, 2018. We received net proceeds totaling $64.5 million from our IPO, $1.6 million in net proceeds from our convertible promissory notes and $0.3 million in proceeds from exercise of stock options.

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.

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 Signatures 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, 2019, 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. 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, 2019.

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 as defined in Exchange Act Rule 13a-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, 2019, 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, 2019, 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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our Board of Directors

The Board is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term. Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors. A director elected by the Board to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified.

The following is a brief biography of each member of our board of directors as of March 26, 2020, with each biography including information regarding experiences, qualification, attributes or skills that caused our board of directors to determine that each member of our board of directors should serve as a director.

Directors Continuing in Office Until the 2020 Annual Meeting

Charles McDermott, 48, has served as a member of our Board since September 2018. Mr. McDermott has served as Chairman, President and Chief Executive Officer of Primmune Therapeutics, Inc., a privately-held biotechnology company, since March 2019. From September 2017 to May 2018, Mr. McDermott served as President and Chief Business Officer of Impact Biomedicines, Inc., a privately-held biotechnology company. Prior to that, Mr. McDermott served as President and Chief Business Officer of Kala Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, from June 2015 to August 2017. Previously, he served as Interim President and Chief Business Officer of Kala from October 2014 to June 2015 and as Executive Vice President of Business Development of Kala from June 2013 to October 2014. Prior to joining Kala, Mr. McDermott served first as Director and then Vice President of Business Development, Eye Care and Drug Delivery at Allergan plc, a publicly-held global pharmaceutical company, where he worked from April 2005 to May 2013. Prior to joining Allergan, Mr. McDermott held a variety of business development positions at deCODE Genetics, Inc. (now DGI Resolutions, Inc.), a privately-held biopharmaceutical company, from January 2001 to March 2005. Prior to deCODE Genetics, Mr. McDermott was a research scientist in the angiogenesis pharmacology group at Agouron Pharmaceuticals, Inc. Mr. McDermott currently serves as an Advisor to Omega Funds, an investment firm that creates and invests in life sciences companies. Mr. McDermott holds an M.B.A. from the University of San Diego, an M.A. in Molecular, Cellular and Developmental Biology from the University of California at Santa Barbara, a B.S. in Biochemistry and Molecular Biology from the University of California Santa Cruz and a Certificate in Clinical Trial Design and Management from the University of California San Diego Extension.

Our Nominating and Corporate Governance Committee and Board believe that Mr. McDermott is qualified to serve on our Board due to his biopharmaceutical and executive experience.

Bruce D. Steel, 53, has served as our President and Chief Executive Officer since January 2020 and as a member of our Board since March 2017. He served as our President and Chief Business Officer from June 2018 through December 2019. Mr. Steel is a co-founder of Equillium. Mr. Steel is the founder and has served as the Managing Director of BioMed Ventures, an investment firm owned by BioMed Realty, LP, since 2010. From 2008 to 2010, Mr. Steel served as the Chief Business Officer at Anaphore, Inc., a privately-held pharmaceutical company. Prior to that, Mr. Steel was co-founder and Chief Executive Officer of Rincon Pharmaceuticals, Inc., a genetic engineering biotechnology company, from 2005 until its acquisition in 2008. Mr. Steel also previously served as the Head of Corporate Development at Ambit Biosciences Corporation from 2002 to 2005. Mr. Steel previously served on the board of directors of Zosano Pharma Corporation, a publicly-held biopharmaceutical company, from 2012 to 2017. Mr. Steel received his B.A. degree from Dartmouth College and M.B.A. degree from the Marshall School of Business at the University of Southern California, and he holds the designation of Chartered Financial Analyst.

Our Nominating and Corporate Governance Committee and Board believe that Mr. Steel is qualified to serve on our Board due to his experience in founding, managing and building companies and investment experience.

Directors Continuing in Office Until the 2021 Annual Meeting

Daniel M. Bradbury, 58, has served as our Executive Chairman of our Board since January 2020 and has been a member and the chairman of our Board since March 2017. He served as our Chief Executive Officer from June 2018 through December 2019. Mr. Bradbury is a co-founder of Equillium and served as our President from March 2017 until June 2018. Mr. Bradbury is the founder and has served as the managing member of BioBrit, LLC, or BioBrit, a life science consulting and investment firm, since September 2012. Mr. Bradbury served as President, Chief Executive Officer and a director of Amylin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, from March 2007 until Amylin's acquisition by Bristol-Myers Squibb Company in August 2012. Prior to Amylin, Mr. Bradbury worked in marketing and sales for 10 years at SmithKline Beecham

Pharmaceuticals, a privately-held pharmaceutical company. Mr. Bradbury serves on the board of directors of numerous private companies and the following publicly-held companies: Castle Biosciences, and Intercept Pharmaceuticals, Inc. Mr. Bradbury previously served on the board of directors of BioMed Realty Trust, Inc., a publicly-held real estate investment trust company, from 2013 to 2016; Corcept Therapeutics Incorporated, a publicly-held biotechnology company, from 2012 to 2019; Geron Corporation, a publicly-held biotechnology company, from 2012 to 2019; Illumina, Inc., a publicly-held biotechnology company, from 2004 to 2017; and Syngene International Ltd., a publicly-held science research company, from 2015 to 2016. Mr. Bradbury holds a Bachelor of Pharmacy from Nottingham University and a Diploma in Management Studies from Harrow and Ealing Colleges of Higher Education in the United Kingdom.

Our Nominating and Corporate Governance Committee and Board believe that Mr. Bradbury's experience as our former Chief Executive Officer and his other executive and board experience, qualifies him to serve as a member of our Board.

Martha J. Demski, 67, has served as a member of our Board since September 2018. From August 2011 to May 2017, Ms. Demski served as Senior Vice President and Chief Financial Officer of Ajinomoto Althea, Inc., now known as Ajinmoto Bio-Pharma Services, a privately-held fully-integrated contract development and manufacturing organization. From July 2008 to December 2010, Ms. Demski served as the Interim Chief Operating Officer and Chief Financial Officer of the Sidney Kimmel Cancer Center, a non-profit corporation that was engaged in biomedical research. Previously, Ms. Demski served as Vice President and Chief Financial Officer of Vical Incorporated, a publicly-held biopharmaceutical company, from December 1989 to June 2004. Ms. Demski currently serves as the chair of the board of directors of Chimerix, Inc., a publicly-held biopharmaceutical company, and on the board of directors, as the chair of the audit committee and as a member of the compensation committee, of Adamas Pharmaceuticals, Inc., a publicly-held biotechnology company. Prior to 2018, Ms. Demski was a member of the board of directors, chair of the audit committee and member of the compensation committee, nominating and governance committee, and operating committee of Neothetics, Inc., a publicly-held biotechnology company that merged with Evofem Biosciences, Inc. in 2018. Ms. Demski is a National Association of Corporate Directors Board Governance Fellow. In 2017, she received the Director of the Year in Corporate Governance award by the Corporate Directors Forum. Additionally, Ms. Demski has over 13 years of banking experience with Bank of America. Ms. Demski earned a B.A. from Michigan State University and an M.B.A. from The University of Chicago Booth School of Business with concentrations in accounting and finance.

Our Nominating and Corporate Governance Committee and Board believe that Ms. Demski is qualified to serve on our Board due to her more than 30 years' experience in the fields of finance and biotechnology as well as her experience as a member of various boards of directors.

Mark Pruzanski, M.D., 52, has served as a member of our Board since September 2018. Dr. Pruzanski is a co-founder and has served as President and Chief Executive Officer and as a member of the board of directors of Intercept Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, since 2002. Dr. Pruzanski has over 20 years of experience in life sciences company management, venture capital and strategic consulting. Prior to co-founding Intercept, Dr. Pruzanski was a venture partner at Apple Tree Partners, an early stage life sciences venture capital firm that he co-founded, and an entrepreneur-in-residence at Oak Investment Partners, a venture capital firm. Dr. Pruzanski is a co-author of a number of scientific publications and is named as an inventor on several patents. Dr. Pruzanski currently serves on the boards of the Emerging Companies Section of the Biotechnology Innovation Organization, a biotechnology-focused trade association, and the Foundation for Defense of Democracies, a non-profit policy institute focusing on foreign policy and national security. Dr. Pruzanski received his M.D. from McMaster University in Hamilton, Canada, a M.A. degree in International Affairs from the Johns Hopkins University School of Advanced International Studies in Bologna, Italy and Washington, D.C., and a bachelor's degree from McGill University in Montreal, Canada.

Our Nominating and Corporate Governance Committee and Board believe that Dr. Pruzanski is qualified to serve on our Board due to his experience in founding, managing and building life sciences companies as well as his venture capital experience.

Directors Continuing in Office Until the 2022 Annual Meeting

Stephen Connelly, Ph.D., 38, has served as our Chief Scientific Officer since January 2018 and as a member of our Board since March 2017. Dr. Connelly is a co-founder of Equillium and served as a consultant from March 2017 until January 2018. Dr. Connelly has served as a principal at BioMed Ventures, an investment firm owned by BioMed Realty, LP, since March 2016. From March 2014 to March 2016, Dr. Connelly served as the Director of Business Development and Therapeutic Alliances at aTyr Pharma, Inc., a publicly-held biotechnology company. Prior to that, Dr. Connelly was a Senior Scientist at The Scripps Research Institute from March 2012 to March 2014, where he worked on multiple drug discovery projects spanning different therapeutic areas. Dr. Connelly has broad experience in conducting novel and innovative research and has published over 30 original scientific papers and patents. Dr. Connelly received a B.S. in Medicinal Chemistry and a Ph.D. in Biological Chemistry from the University of Exeter, United Kingdom, and an M.B.A. from the Rady School at University of California, San Diego.

Our Nominating and Corporate Governance Committee and Board believe that Dr. Connelly's scientific and research expertise qualify him to serve on our Board.

Bala S. Manian, Ph.D., 74, has served as a member of our Board since May 2017. Dr. Manian has served on the board of directors of Syngene International Ltd., a publicly-held contract research and manufacturing organization based in India, since June 2015. Dr. Manian has served as Chief Executive Officer and chairman of the board of directors of ReaMatrix, Inc., a privately-held biotechnology company, since 2004. Dr. Manian has served as Executive Chairman of LeukoDx Inc., a privately-held biotechnology company, since May 2017. Dr. Manian founded and served as chairman of the board of directors of Lumisys Incorporated, a publicly-held medical systems company, from 1987 to 1994, of Molecular Dynamics, Inc., a publicly-held genetic discovery and analysis company, from 1987 to 1994, and of Biometric Imaging, Inc., a privately-held biotechnology company, from 1993 to 1998. Dr. Manian also co-founded Quantum Dot Corporation and SurroMed Inc. Dr. Manian received a B.S. in Physics from Loyola College, Chennai, a postgraduate level Diploma in Instrumentation from the Madras Institute of Technology, Chennai, an M.S. in Applied Optics from the University of Rochester, and a Ph.D. in Mechanical Engineering from Purdue University.

Our Nominating and Corporate Governance Committee and Board believe that Dr. Manian's experience in founding, managing, and building companies and scientific and research experience qualify him to serve on our Board.

BOARD LEADERSHIP STRUCTURE

Our Board is currently chaired by our Executive Chairman, Mr. Bradbury. In January 2020, Mr. Bradbury transitioned from his prior role of Chief Executive Officer to Executive Chairman of our Board of Directors. With Mr. Bradbury's extensive history with and knowledge of our company, we believe his role as our Executive Chairman will facilitate a regular flow of information between the Board and management and ensure that they both act with a common purpose. Our Board does not have a lead independent director.

ROLE OF THE BOARD IN RISK OVERSIGHT

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for us. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements, in addition to oversight of the performance of our internal audit function. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

MEETINGS OF THE BOARD OF DIRECTORS

The Board met five times and acted by unanimous written consent two times during 2019. All directors attended at least 75% of the aggregate number of meetings of the Board and of the committees on which they served during 2019.

INFORMATION REGARDING COMMITTEES OF THE BOARD OF DIRECTORS

The Board has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The following table provides membership and meeting information for fiscal year 2019 for each of these committees of the Board:

Name	Audit	Compensation	Nominating and Corporate Governance
Martha J. Demski	X*	X	
Bala S. Manian, Ph.D.	X	X*	
Charles McDermott	X		X*
Mark Pruzanski, M.D.			X
Total meetings in 2019	8	5	2

* Committee Chairperson

Below is a description of each committee of the Board.

Each of the committees has authority to engage legal counsel or other experts or consultants, as it deems appropriate to carry out its responsibilities. The Board has determined that each member of each committee meets the applicable Nasdaq rules and regulations regarding "independence" and that each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to us.

Audit Committee

The Audit Committee of the Board was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act, to oversee our corporate accounting and financial reporting processes and audits of its financial statements. For this purpose, the Audit Committee performs several functions, including, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing, with our independent auditors and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related-person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management are implemented;
- reviewing, on a periodic basis, our investment policy; and
- reviewing and evaluating, on an annual basis, the performance of the Audit Committee and the Audit Committee charter.

The Audit Committee is composed of three directors: Ms. Demski (chair), Dr. Manian and Mr. McDermott. The Audit Committee met eight times during the 2019 fiscal year. The Board has adopted a written Audit Committee charter that is available to stockholders 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.

The Board reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of our Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards and Rule 10A-3 of the Exchange Act).

The Board has also determined that Ms. Demski qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of Ms. Demski's level of knowledge and experience based on a number of factors, including her formal education, prior experience, business acumen and independence.

Report of the Audit Committee of the Board of Directors*

The Audit Committee has reviewed and discussed the audited consolidated financial statements for the fiscal year ended December 31, 2019 with our management. The Audit Committee has discussed with the independent registered public accounting firm the matters required to be discussed under the applicable requirements of the Public Company Accounting Oversight Board, or PCAOB, and Securities and Exchange Commission. The Audit Committee has also received the written disclosures and the letter from the independent registered public accounting firm required by applicable requirements of the PCAOB regarding the independent registered public accounting firm's communications with the Audit Committee concerning independence, and has discussed with the independent registered public accounting firm the accounting firm's independence. Based on the foregoing, the Audit Committee has recommended to the Board that the audited consolidated financial statements be included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

Martha J. Demski (Chair)
Bala S. Manian, Ph.D.
Charles McDermott

** The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any of our filings under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

Compensation Committee

The Compensation Committee of the Board is composed of two directors: Dr. Manian (chair) and Ms. Demski. Our Board has determined that each of the members of our Compensation Committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and satisfies the Nasdaq independence requirements. The Compensation Committee met five times during the 2019 fiscal year and acted by written consent two times during the 2019 fiscal year. The Board has adopted a written Compensation Committee charter that is available to stockholders 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.

The Compensation Committee acts on behalf of the Board to review, adopt or recommend to the Board for adoption, and oversee our compensation strategy, policies, plans and programs. For this purpose, the Compensation Committee performs several functions, including, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board regarding) our overall compensation strategy and policies;
- reviewing and making recommendations to the full Board regarding the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems appropriate, making recommendations to the full Board regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems appropriate, making recommendations to the full Board regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full Board regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation to the extent required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisers as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full Board regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing, on an annual basis, the performance of the Compensation Committee and the Compensation Committee charter.

Compensation Committee Processes and Procedures

Typically, the Compensation Committee meets at least three times per year and with greater frequency, if necessary. The agenda for each meeting is usually developed by the Chair of the Compensation Committee, in consultation with management. The Compensation Committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, to provide financial or other background information or advice or to otherwise participate in Compensation Committee meetings. The Chief Executive Officer does not participate in, and is not present during, any deliberations or determinations of the Compensation Committee regarding his compensation or individual performance objectives. The charter of the Compensation Committee grants the Compensation Committee full access to all books, records, facilities and our personnel. In addition, under its charter, the Compensation Committee has the authority to obtain, at our expense, advice and assistance from internal and external legal, accounting or other advisers and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. The Compensation Committee has direct responsibility for the oversight of the work of any advisers engaged for the purpose of advising the Compensation Committee. In particular, the Compensation Committee has the sole authority to retain compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant’s reasonable fees and other retention terms. Under its charter, to the extent required by SEC and Nasdaq rules, the Compensation Committee may select, or receive advice from, a compensation consultant, legal counsel or other adviser to the Compensation Committee, other than in-house legal counsel and certain other types of advisers, only after taking into consideration six factors, prescribed by the SEC and Nasdaq, that bear upon the adviser’s independence; however, there is no requirement that any adviser be independent.

In January 2019, after taking into account the six factors prescribed by the SEC and Nasdaq described above, we engaged Radford, an Aon Hewitt Company, as its compensation consultant. Radford was retained to provide an assessment of our executive and director compensation programs in comparison to executive and director compensation programs at selected publicly-traded peer companies. As part of its engagement, Radford was requested by the Compensation Committee to develop the peer group of comparative companies and to perform analyses of compensation levels for that group. Radford developed peer group and related recommendations that were presented to the Compensation Committee for its consideration in evaluating and approving salary, bonus and equity compensation decisions for our named executive officers during 2019. The publicly-traded peer companies selected and used as part of Radford’s market compensation analysis were: AVROBIO, Inc., Calithera Biosciences, Inc., Catalyst Biosciences, Inc., Conus Pharmaceuticals, Inc., Enochian Biosciences, Inc., Kezar Life Sciences, Inc., Mersana Therapeutics, Inc., Pfenex Inc., PhaseBio Pharmaceuticals, Inc., Pieris Pharmaceuticals, Inc., Protagonist Therapeutics, Inc., Spring Bank Pharmaceuticals. Inc., Selecta Biosciences, Inc., Spero Therapeutics, Inc., Syros Pharmaceuticals, Inc., Synthoxx, Inc., Tocagen, Inc., Unum Therapeutics Inc., and Zafgen, Inc. In August 2020, the Compensation Committee engaged Radford as its compensation consultant to undertake a market comparison analysis to assist with evaluating salary, bonus and equity compensation for our executives, including our named executive officers, for 2020.

The Compensation Committee holds one or more meetings at the end of the year and/or during the first quarter of the year to discuss and make recommendations to the Board for annual compensation adjustments, annual bonuses, annual equity awards, and new corporate performance objectives. However, the Compensation Committee also considers matters related to individual compensation, such as compensation for new executive hires, as well as high-level strategic issues, such as the efficacy of our compensation strategy, potential modifications to that strategy and new trends, plans or approaches to compensation, at various meetings throughout the year. Generally, the Compensation Committee’s process comprises two related elements: the determination of compensation levels and the establishment of performance objectives for the current year. For executives other than the Chief Executive Officer, the Compensation Committee solicits and considers evaluations and recommendations submitted to the Compensation Committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the Compensation Committee. For all executives and directors as part of its deliberations, the Compensation Committee may review and consider, as appropriate, materials such as financial reports and projections, operational data, tax and accounting information, tally sheets that set forth the total compensation that may become payable to executives in various hypothetical scenarios, executive and director stock ownership information, company stock performance data, analyses of historical executive compensation levels and current Company-wide compensation levels, compensation data from comparative companies, compensation surveys, and recommendations of any compensation consultant, if applicable.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee of the Board is responsible for identifying, reviewing and evaluating candidates to serve as our directors (consistent with criteria approved by the Board), reviewing and evaluating incumbent directors, selecting or recommending to the Board for selection candidates for election to the Board, making recommendations to the Board regarding the membership of the committees of the Board, assessing the performance of the Board, and developing a set of corporate governance principles for us.

The Nominating and Corporate Governance Committee is composed of two directors: Mr. McDermott (chair) and Dr. Pruzanski. Both members of the Nominating and Corporate Governance Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the Nasdaq listing standards). The Nominating and Corporate Governance Committee met two times during the 2019 fiscal year. The Board has adopted a written Nominating and Corporate Governance Committee charter that is available to stockholders 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. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our Board, consistent with criteria approved by our Board;
- determining the minimum qualifications for service on our Board;
- evaluating director performance on the Board and applicable committees of the Board and determining whether continued service on our Board is appropriate;
- evaluating, nominating and recommending individuals for membership on our Board;
- evaluating nominations by stockholders of candidates for election to our Board;
- considering and assessing the independence of members of our Board;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our Board any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and assessing on an annual basis the performance of the Nominating and Corporate Governance Committee and the Nominating and Corporate Governance Committee charter.

The Nominating and Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including the ability to read and understand basic financial statements, being over 21 years of age and having the highest personal integrity and ethics. The Nominating and Corporate Governance Committee also considers such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to our affairs, demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of our stockholders. However, the Nominating and Corporate Governance Committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of the Board, our operating requirements and the long-term interests of our stockholders. In conducting this assessment, the Nominating and Corporate Governance Committee typically considers diversity (including gender, racial and ethnic diversity), age, skills and such other factors as it deems appropriate, given the current needs of the Board and us, to maintain a balance of knowledge, experience and capability.

The Nominating and Corporate Governance Committee appreciates the value of thoughtful Board refreshment, and regularly identifies and considers qualities, skills and other director attributes that would enhance the composition of the Board. In the case of incumbent directors whose terms of office are set to expire, the Nominating and Corporate Governance Committee reviews these directors' overall service to us during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. In the case of new director candidates, the Nominating and Corporate Governance Committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The Nominating and Corporate Governance Committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The Nominating and Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. The Nominating and Corporate Governance Committee meets to discuss and consider the candidates' qualifications and then selects candidates for recommendation to the Board by majority vote.

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. The Nominating and Corporate Governance Committee does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Nominating and Corporate Governance Committee to become nominees for election to the Board may do so by delivering a written recommendation to the Nominating and Corporate Governance Committee at the following address: c/o Equillium, Inc., 2223 Avenida de la Playa, Suite 105, La Jolla, California 92037, Attn: Secretary, no later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting. Submissions must include the name and address of our stockholder on whose behalf the submission is made; the number of Company shares that are owned beneficially by such stockholder as of the date of the submission; the full name of the proposed candidate; a description of the proposed candidate's business experience for at least the previous five years; complete biographical information for the proposed candidate; and a description of the proposed candidate's qualifications as a director. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected.

STOCKHOLDER COMMUNICATIONS WITH THE BOARD OF DIRECTORS

The Board has adopted a formal process by which stockholders may communicate with the Board or any of its directors. Stockholders who wish to communicate with the Board may do so by sending written communications addressed to the Secretary of Equillium, Inc., 2223 Avenida de la Playa, Suite 105, La Jolla, California 92037. These communications will be reviewed by the Secretary of Equillium who will determine whether the communication is appropriate for presentation to the Board or the relevant director. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

CODE OF ETHICS

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 its website or in a current report on Form 8-K.

Our Executive Officers

Bruce D. Steel, 53, has served as our President and as our Chief Executive Officer since January 2020 and as a member of our Board since March 2017. Mr. Steel served as our President and Chief Business Officer from June 2018 through December 2019. For additional information regarding Mr. Steel's industry experience and education, see above under "Directors Continuing in Office Until the 2020 Annual Meeting."

Stephen Connelly, Ph.D., 38, has served as our Chief Scientific Officer since January 2018 and as a member of our Board since March 2017. For additional information regarding Dr. Connelly's industry experience and education, see above under "Nominees for Election for a Three-year Term Expiring at the 2022 Annual Meeting."

Jason A. Keyes, 49, has served as our Chief Financial Officer since March 2018. From January 2013 to February 2018, Mr. Keyes held positions of increasing responsibility at Orexigen Therapeutics, Inc., a publicly-held pharmaceutical company which filed a voluntary petition for Chapter 11 bankruptcy in March 2018, most recently as Executive Vice President and Chief Financial Officer. Mr. Keyes held positions of increasing responsibility at Amylin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, from August 2007 until January 2013, most recently as Senior Director of Finance. Prior to joining Amylin, Mr. Keyes held positions of increasing responsibility in finance and corporate strategy at Amgen Inc., a publicly-held biopharmaceutical company, and Baxter Healthcare Corporation, a publicly-held healthcare company. Mr. Keyes has served as a director of Sesen Bio, Inc., a publicly-held biopharmaceutical company, since February 2020. Mr. Keyes received his B.S. and M.S. degrees in Civil Engineering from Stanford University and an M.B.A. from the Anderson School at the University of California, Los Angeles.

Krishna R. Polu, M.D., 47, has served as our Executive Vice President, Research and Development since January 2020. Dr. Polu served as our Chief Medical Officer from August 2018 through December 2019. From February 2018 to August 2018, Dr. Polu served as Interim Chief Executive Officer of Scout Bio, Inc., a privately-held biotechnology company. Dr. Polu founded Expedition Therapeutics, Inc., a privately-held search company, in June 2017 and served as its Chief Executive Officer from June 2017 until August 2018. Dr. Polu also served as an Entrepreneur-in-Residence at Frazier Healthcare Partners, an investment firm, from February 2017 until August 2018. Prior to that, Dr. Polu served as the Chief Medical Officer of Raptor Pharmaceutical Corp., a publicly-held biopharmaceutical company, from January 2015 to December 2016. Dr. Polu also previously served as the Chief Medical Officer of CytomX Therapeutics, Inc., a privately-held biotechnology company, from

March 2013 to June 2014. From July 2009 to March 2013, Dr. Polu served as Vice President of Clinical Development at Affymax, Inc., a publicly-held biopharmaceutical company. Prior to Affymax, Inc., Dr. Polu served as the Executive Director, Global Development of Amgen Inc., a publicly-held biotechnology company, from November 2007 to July 2009. Dr. Polu holds a B.A. in Human Biology from Stanford University and a M.D. from University of Texas Health Science Center, San Antonio. Dr. Polu also completed an internal medicine internship and residency at the University of Colorado as well as clinical and research fellowships in nephrology and transplant at Harvard Medical School in a joint program with Brigham and Women's Hospital and Massachusetts General Hospital.

Christine Zedelmayer, 50, has served as Senior Vice President, Chief Operating Officer since January 2020. Ms. Zedelmayer served as our Vice President of Operations from February 2018 through December 2019. Prior to Equillium, Ms. Zedelmayer was owner and principal consultant at Centerra Consulting, LLC, a project management and investor relations consulting firm focused on life sciences, from 2012 to February 2018, where she led strategic business development projects for clients and served as head of investor relations for a variety of medical device companies. Prior to Centerra, from 2003 to 2012, Ms. Zedelmayer held a variety of roles at Amylin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, including Senior Director of Alliance Management, where she led the global collaboration with Eli Lilly and as Executive Director of Investor Relations. Before joining Amylin, Ms. Zedelmayer held various leadership positions within project management at Amgen Inc., a publicly-held biopharmaceutical company, Ligand Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, and Hybritech, Inc., a privately-held medical diagnostics company. Ms. Zedelmayer received her B.S. in Electrical Engineering at San Diego State University and a M.B.A. with Finance emphasis at California Lutheran University.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2019, which consist of our principal executive officer and our two other most highly compensated executive officers, were:

- Daniel M. Bradbury*, our Executive Chairman of the Board and former Chief Executive Officer;
- Krishna R. Polu, M.D.**, our Executive Vice President, Research and Development and Chief Medical Officer; and
- Bruce D. Steel***, our President and Chief Executive Officer and former Chief Business Officer.

*Mr. Bradbury transitioned from our Chief Executive Officer to our Executive Chairman of the Board as of January 1, 2020.
**Dr. Polu was promoted from Chief Medical Officer to Executive Vice President, Research and Development and Chief Medical Officer as of January 1, 2020.
***Mr. Steel transitioned from our Chief Business Officer to our Chief Executive Officer as of January 1, 2020.

Summary Compensation Table

The following table shows the compensation earned by our named executive officers for the fiscal years ended December 31, 2019 and December 31, 2018.

Name and principal position	Year	Salary ($)	Option awards ($)(1)	Non-equity incentive plan compensation ($)(2)	Total ($)
Daniel M. Bradbury (3)	2019	425,000	625,365	153,000	1,203,365
Executive Chairman of the Board of Directors; former Chief Executive Officer	2018	233,333	—	81,667	315,000
Krishna R. Polu, M.D.	2019	409,375	951,372	147,375	1,508,122
Executive Vice President, Research and Development and Chief Medical Officer	2018	143,750	2,148,408	43,125	2,335,283
Bruce D. Steel (4)	2019	395,833	820,535	142,500	1,358,868
President and Chief Executive Officer; former Chief Business Offer	2018	218,750	—	76,563	295,313

(1) In accordance with SEC rules, amounts shown in this column reflect the aggregate grant date fair value of the stock option awards computed in accordance with Financial Accounting Standard Board, or FASB, Accounting Standards Codification Topic 718 for stock-based compensation transactions, or ASC 718. Assumptions used in the calculation of these amounts are described in Note 9 to our audited financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2019. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) The 2019 amounts shown in this column represent performance bonuses earned in 2019, which were paid in cash in March 2020. The 2018 amounts shown in this column represent performance bonuses earned in 2018, which were paid in cash in January 2019.

(3) Mr. Bradbury was our Chief Executive Officer from June 1, 2018 through December 31, 2019. Effective as of January 1, 2020, Mr. Bradbury transitioned from Chief Executive Officer to Executive Chairman of our Board of Directors.

(4) Mr. Steel joined us on June 1, 2018 as our President and Chief Business Officer. Accordingly, the salary and non-equity incentive plan compensation amounts listed for Mr. Steel for 2018 represent compensation earned from June 1, 2018 through December 31, 2018. Effective as of January 1, 2020, Mr. Steel transitioned from Chief Business Officer to Chief Executive Officer.

Compensation Program Overview

Our compensation program for executive officers is designed to encourage our management team to continually achieve our short-term and long-term corporate objectives while effectively managing business risks and challenges. We provide what we believe is a competitive total compensation package to our management team through a combination of base salary, an annual performance-based bonus and long-term equity-based incentives.

Annual Base Salary

The 2019 annual base salaries for our named executive officers are provided below:

Name	2019 Base Salary ($)
Daniel M. Bradbury	430,000*
Krishna R. Polu, M.D.	425,000**
Bruce D. Steel	400,000

* In March 2019, the Compensation Committee approved an increase in the annual base salary for Mr. Bradbury from $400,000 to $430,000.

** In March 2019, the Compensation Committee approved an increase in the annual base salary for Dr. Polu from $375,000 to $400,00. In June 2019, the Compensation Committee approved an additional increase in the annual base salary for Dr. Polu to $425,000.

In December 2019, the Compensation Committee approved an increase in the annual base salary for Dr. Polu to $450,000 in connection with his transition to Executive Vice President, Research and Development and Chief Medical Officer. Mr. Bradbury's annual base salary was decreased to $150,000 in connection with his transition to Executive Chairman of our Board. These changes to annual base salaries were effective as of January 1, 2020. Mr. Steel's annual base salary remained the same for 2020.

Bonus Compensation

With respect to 2019, each of our named executive officers were eligible to receive a performance-based bonus based on the attainment of individual and corporate objectives. The 2019 performance-based bonus awards were determined by multiplying the bonus target opportunity for each named executive officer by a corporate performance factor established by our Compensation Committee based on our performance as measured against our corporate goals and additional unanticipated performance achievements during the year. The Compensation Committee sets the target bonus opportunity at the beginning of the year, based primarily on data provided by Radford.

The target bonus opportunity as a percentage of 2019 base salary for each of our named executive officers is as follows:

Name	2019 Target Bonus (% of annual base salary)
Daniel M. Bradbury	40%
Krishna R. Polu, M.D.	40%*
Bruce D. Steel	40%

* In June 2019, the Compensation Committee approved increasing the target bonus opportunity for Dr. Polu from 37.5% to 40%, effective as of January 1, 2019.

In February 2020, the Compensation Committee reviewed our corporate performance and noted that we made substantial progress on our clinical development and business goals, as well as achieved various additional accomplishments during 2019. Such progress included the following:

- Initiated a Phase 1b/2 clinical trial for the treatment of aGVHD and received Orphan Drug designations for the prevention and treatment of GVHD in the first quarter of 2019;
- Initiated a Phase 1b proof-of-concept clinical trial for the treatment of uncontrolled moderate to severe asthma in the second quarter of 2019;
- Initiated a Phase 1b proof-of-concept clinical trial for the treatment of lupus nephritis in the third quarter of 2019 and secured Fast Track designation for the treatment of lupus nephritis in the fourth quarter of 2019;
- Completed various translational studies to support our clinical development program and raise the awareness of the CD6-ALCAM pathway;
- Secured a term debt facility for up to $20.0 million in three tranches from Oxford Finance LLC and Silicon Valley Bank to further capitalize the company in the third quarter of 2019;
- Expanded existing license agreement with Biocon to include development and commercialization rights in Australia and New Zealand in the fourth quarter of 2019; and
- Secured exclusive rights from Biocon to negotiate licensing rights with third parties to develop and commercialize itolizumab in select major markets outside of North America in the third quarter of 2019.

As a result, the Compensation Committee approved 2019 performance cash bonus payments to our named executive officers based on an assessment of corporate performance during 2019. Mr. Bradbury was awarded a $153,000 bonus, Dr. Polu was awarded a $147,375 bonus and Mr. Steel was awarded a $142,500 bonus, in each case in recognition of a 90% performance achievement level.

Also, in December 2019, the Compensation Committee approved increasing the target bonus opportunity for 2020 for Mr. Steel from 40% to 60% in connection with his transition to President and Chief Executive Officer and reduced Mr. Bradbury's target bonus opportunity to 0% in connection with his transition to Executive Chairman of our Board. Dr. Polu's target bonus opportunity for 2020 remained unchanged at 40%.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees and consultants, including our named executive officers. The Board and Compensation Committee are responsible for approving equity grants. To date, stock option awards are the only form of equity awards we have granted to our named executive officers.

We have historically used stock options as an incentive for long-term compensation to our named executive officers because they are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, which exercise price is set at the fair market value of our common stock on the date of grant. We may grant equity awards at such times as our Board and/or Compensation Committee determines appropriate. Other than our founders, our executive officers generally are awarded an initial grant in the form of a stock option in connection with their commencement of employment with us. Additional grants may occur periodically in order to retain and specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to our initial public offering in October 2018, we granted all stock options pursuant to our 2017 Equity Incentive Plan, or 2017 Plan. Following our initial public offering, we have granted and will grant equity incentive awards under the terms of our 2018 Equity Incentive Plan, or 2018 Plan. The terms of the 2017 Plan and the 2018 Plan are described below under "—Equity Benefit Plans."

All options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award. Our stock option awards generally vest over a four-year period subject to continued service and may be subject to acceleration of vesting and exercisability under certain termination and change in control events. See "— Outstanding Equity Awards at Fiscal Year-End."

In February 2019, the Compensation Committee granted options to purchase 90,000 shares of our common stock to each of Mr. Bradbury and Dr. Polu and an option to purchase 44,352 shares of our common stock to Mr. Steel at an exercise price of $7.16 per share. In addition, in February 2019, the Compensation Committee granted an option to purchase 45,648 shares of our common stock to Mr. Steel at an exercise price of $7.88 per share. Each of the options vests as to 25% of the shares on February 13, 2020 with the balance of shares vesting in approximately equal monthly installments over the remaining 36 months, subject to the respective named executive officer's continued service with us and subject to full acceleration of all of the shares in the event the respective named executive officer is terminated by us without cause or resigns for good reason within 12 months after a change in control.

Additionally, in December 2019, the Compensation Committee granted options to purchase 36,000, 100,000 and 125,000 shares of our common stock to Messrs. Bradbury and Steel and Dr. Polu, respectively, at an exercise price of $4.75 per share. Each of the options vests as to 25% of the shares on December 10, 2020 with the balance of shares vesting in approximately equal monthly installments over the remaining 36 months, subject to the respective named executive officer's continued service with us and subject to full acceleration of all of the shares in the event the respective named executive officer is terminated by us without cause or resigns for good reason within 12 months after a change in control.

Agreements with our Named Executive Officers

We have entered into offer letter agreements with each of our named executive officers which are described below. For a discussion of the severance pay and other benefits available in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, please see "—Potential Payments Upon Termination or Change in Control" below. In addition, each of our named executive officers is eligible to participate in the employee benefit plans generally available to our employees.

Daniel M. Bradbury. In June 2018, we entered into an offer letter with Mr. Bradbury, which governs the terms of his employment with us. The offer letter provides for an initial annual base salary and eligibility to receive an annual performance-based bonus, based on the attainment of individual and corporate objectives to be determined and approved by us. In December 2019, the Compensation Committee, in connection with Mr. Bradbury's transition to Executive Chairman of our Board, approved decreasing Mr. Bradbury's annual base salary to $150,000 and reduced his target bonus opportunity to 0%.

Krishna R. Polu, M.D. In August 2018, we entered into an offer letter with Dr. Polu, which governs the terms of his employment with us. The offer letter provides for an initial annual base salary and eligibility for an annual performance-based bonus, based on the attainment of individual and corporate objectives to be determined and approved by us. The offer letter also provided for an initial stock option which was granted in August 2018. The offer letter also contemplates that Dr. Polu will, at our discretion, be reimbursed for up to $50,000 per year, subject to adjustment based on our business needs, to commute to our offices in La Jolla.

Bruce D. Steel. In June 2018, we entered into an offer letter with Mr. Steel, which governs the terms of his employment with us. The offer letter provides for an initial annual base salary and eligibility for an annual performance-based bonus, based on the attainment of individual and corporate objectives to be determined and approved by us.

Potential Payments and Benefits upon Termination or Change in Control

Each of our named executive officer's employment is at will and may be terminated by us at any time. Regardless of the manner in which the named executive officer's service terminates, such named executive officer is entitled to receive any and all accrued but unpaid amounts earned during his or her term of service, including unpaid salary, as applicable. In addition, the offer letter agreements with each of Mr. Bradbury, Dr. Polu and Mr. Steel each provide that, if we terminate such named executive officer's employment without cause, the named executive officer is entitled to receive (i) continuation of the applicable named executive officer's then-current base salary for six months and (ii) payment of the premiums for group health insurance COBRA continuance coverage for six months or, if earlier, until the date on which the named executive officer becomes eligible to receive comparable benefits from another employer.

Additionally, if we terminate the named executive officer's employment without cause within one month prior to, or 12 months following, certain change of control and asset sale transactions, the named executive officer is entitled to receive (i) continuation of the applicable named executive officer's then-current base salary for 12 months, (ii) an amount equal to the applicable named executive officer's target annual bonus and (iii) payment of the premiums for group health insurance COBRA continuance coverage for 12 months or, if earlier, until the date on which the named executive officer becomes eligible to receive comparable benefits from another employer. In each case, the severance benefits are conditioned upon the execution and non-revocation of a general release of claims by the applicable named executive officer in a form provided by us. Our named executive officers are also entitled to "double trigger" vesting acceleration upon their respective terminations in connection with a change in control, as described above under "—Equity Based Incentive Awards".

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding equity awards granted to our named executive officers that remain outstanding as of December 31, 2019:

	Option Awards[1]				
	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)[2]	Option Expiration Date
Daniel M. Bradbury	2/13/2019	—	90,000	$ 7.16	2/12/2029
	12/10/2019	—	36,000	$ 4.75	12/9/2029
Krishna R. Polu, M.D.	8/16/2018	208,216	—	$ 3.30	8/15/2028
	2/13/2019	—	90,000	$ 7.16	2/12/2029
	12/10/2019	—	125,000	$ 4.75	12/9/2029
Bruce D. Steel	2/13/2019	—	44,352	$ 7.16	2/12/2029
	2/13/2019	—	45,648	$ 7.88	2/12/2024
	12/10/2019	—	100,000	$ 4.75	12/9/2029

(1) With the exception of Dr. Polu's August 2018 stock option award, all of the outstanding stock option awards were granted under and subject to the terms of the 2018 Plan, the terms of which are described below under "— Equity Benefit Plans." Dr. Polu's August 2018 stock option award was granted under and subject to the terms of the 2017 Plan, the terms of which are described below under "— Equity Benefit Plans."

(2) All of the stock option awards were granted with a per share exercise price at least equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our Board. Unless otherwise noted, all options granted provide for the following "standard" vesting schedule: 25% of the shares subject to the option vest on the 12-month anniversary of the grant date and the remaining shares subject to the option vest in equal monthly installments over the next three years subject to the named executive officer's continued service to us. The options are subject to potential vesting acceleration as described above under "— Agreements with our Named Executive Officers" and "— Potential Payments and Benefits Upon Termination or Change in Control."

Option Repricings

We did not engage in any repricings or other modifications or cancellations to any of our named executive officers' outstanding equity awards during the fiscal year ended December 31, 2019.

Perquisites Health, Welfare and Retirement Benefits

Our named executive officers, during their employment with us, are eligible to participate in our employee benefit plans, including our medical, dental, group term life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. In addition, we provide a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled "—401(k) Plan."

We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. We do, however, pay the premiums for medical, dental, group term life, disability and accidental death and dismemberment insurance for all of our employees, including our named executive officers. Our Board may elect to adopt qualified or nonqualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the U.S. Internal Revenue Code of 1986, as amended, or the Code. The 401(k) plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which was $19,000 for calendar year 2019. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2019 was up to an additional $6,000 above the statutory limit. We currently do not make matching contributions into the 401(k) plan on behalf of participants. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

Nonqualified Deferred Compensation

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our Board may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future, if it determines that doing so is in our best interests.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2019.

	Equity Compensation Plan Information		
Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c) (1)
Equity compensation plans approved by stockholders (2)	1,821,093	$ 5.64	1,317,189
Equity compensation plans not approved by stockholders (3)	—	$ —	—
Total	1,821,093		1,317,189

(1) Under the terms of the 2018 Plan, the number of shares of our 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 our 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 our board of directors. Under the terms of our 2018 Employee Stock Purchase Plan, or ESPP, the number of shares of our 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 our 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, our board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2).

(2) Includes the 2017 Plan, the 2018 Plan and our 2018 Employee Stock Purchase Plan, or the ESPP. 503,716 shares under column (c) are attributable to our ESPP.

(3) As of December 31, 2019, we did not have any equity compensation plans that were not approved by our stockholders.

Equity Benefit Plans

2018 Equity Incentive Plan

Our Board adopted our 2018 Plan in October 2018 and our stockholders approved our 2018 Plan in October 2018. The 2018 Plan became effective on October 11, 2018 in connection with our initial public offering. The 2018 Plan is a successor to and continuation of our 2017 Plan. No further grants will be made under the 2017 Plan.

Our 2018 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates.

Our Compensation Committee administers our 2018 Plan and is referred to as the “plan administrator” herein. Our Board or Compensation Committee may also delegate certain limited authority to one or more of our officers.

ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2018 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2018 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2018 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Our 2018 Plan provides that in the event of certain specified significant corporate transactions (or a change in control, as defined in the 2018 Plan), unless otherwise provided in an award agreement or other written agreement between us and the award holder, the plan administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- accelerate the vesting, in whole or in part, of the stock award and provide for its termination if not exercised (if applicable) at or before the effective time of the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised before the effective time of the transaction, in exchange for a cash payment, if any; or
- make a payment equal to the excess, if any, of (A) the value of the property the participant would have received on exercise of the award immediately before the effective time of the transaction, over (B) any exercise price payable by the participant in connection with the exercise.

The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

In the event of a change in control, the plan administrator may take any of the above-mentioned actions. Awards granted under the 2018 Plan may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

2017 Equity Incentive Plan

Our Board and our stockholders approved our 2017 Plan in December 2017. No further awards may be granted under the 2017 Plan, and all outstanding awards granted under the 2017 Plan that are repurchased, forfeited, expire or are canceled will become available for grant under the 2018 Plan in accordance with its terms.

Our 2017 Plan provided for the grant of ISOs within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of NSOs, stock appreciation rights, restricted stock, restricted stock units and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates.

Our Compensation Committee administers our 2017 Plan and is referred to as the "plan administrator" herein.

If an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of up to three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws or our insider trading policy.

If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of up to 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of up to 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Our 2017 Plan provides that in the event of a "corporate transaction" (as defined in the 2017 Plan) unless otherwise provided in an award agreement or other written agreement between us and the award holder, the plan administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a surviving or acquiring corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring corporation;

- accelerate the vesting, in whole or in part, of the stock award and provide for its termination if not exercised (if applicable) at or before the effective time of the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award, to the extent not exercised before the effective time of the transaction, in exchange for a payment in such form as may be determined by our Board, equal to the excess, if any, of (A) the per share amount (or value of property per share) payable to holders of common stock in connection with the transaction, over (B) the per share exercise price under the stock award (if any), multiplied by the number of vested shares subject to the stock award;
- make a payment equal to the excess, if any, of (A) the value of the property the participant would have received on exercise of the award immediately before the effective time of the transaction, over (B) any exercise price payable by the participant in connection with the exercise;
- suspend the exercise of the stock award, prior to the effective time of the transaction, for such period as our Board determines is necessary to facilitate the negotiation and consummation of the transaction; and
- if a stock award is eligible for "early exercise," cancel or arrange for the cancellation of any such "early exercise" rights upon the transaction, such that following the transaction, such stock award may only be exercised to the extent vested.

The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to treat all participants in the same manner.

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in an applicable award agreement or other written agreement, but in the absence of such provision, no such acceleration will occur.

2018 Employee Stock Purchase Plan

Our Board adopted, and our stockholders approved, our ESPP in October 2018 and the ESPP became effective on October 11, 2018 in connection with our initial public offering. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code for U.S. employees.

Our Compensation Committee administers the ESPP. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP, subject to certain limitations set forth in the ESPP of offering document thereunder. Unless otherwise determined by our Compensation Committee or Board, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of our common stock on the first date of an offering, or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

In the event of certain significant corporate transactions (as defined in the ESPP), any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately.

Director Compensation

Prior to our initial public offering in 2018, we did not pay cash compensation to any of our non-employee directors for service on our Board. However, we did pay equity compensation to our non-employee directors for service on our Board. We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our Board and committees of our Board.

On June 11, 2019, we granted each of Drs. Manian and Pruzanski, Ms. Demski and Mr. McDermott an option to purchase 12,000 shares of common stock at an exercise price of $6.01 per share. Such option vests in 12 successive equal monthly installments beginning on June 11, 2019, subject to their continued service with us.

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2019 to each of our directors that was not also a named executive officer:

Name (1)	Fees Earned or Paid in Cash ($)	Option Awards ($)(2)(3)	Total ($)
Stephen Connelly, Ph.D.	—	—	—
Martha J. Demski	60,000	53,230	113,230
Bala S. Manian, Ph.D.	57,500	53,230	110,730
Charles McDermott	55,500	53,230	108,730
Mark Pruzanski, M.D.	44,000	53,230	97,230

(1) Mr. Bradbury, Mr. Steel and Dr. Connelly did not earn compensation during 2019 for their services on the Board. Mr. Bradbury's and Mr. Steel's compensation is fully reflected in the "— Summary Compensation Table" above.

(2) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the stock option awards granted in 2019 computed in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are described in Note 9 to our audited financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2019. These amounts do not reflect the actual economic value that will be realized by the non-employee director upon the vesting of the stock option awards, the exercise of the stock option awards or the sale of the common stock underlying such stock option awards.

(3) As of December 31, 2019, the aggregate number of shares subject to outstanding options to purchase our common stock held by our non-employee directors was as follows: 12,000 shares for Ms. Demski, 12,000 shares for Dr. Manian, 12,000 shares for Mr. McDermott and 12,000 shares for Dr. Pruzanski.

Our Board adopted a director compensation policy in June 2019 that became effective on June 10, 2019 and is applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our Board:

- an annual cash retainer of $40,000;
- an additional cash retainer of $20,000 to the chairman of the Board;
- an additional annual cash retainer of $7,500, $5,000 and $4,000 for service as a member of the Audit Committee, Compensation Committee and the Nominating and Corporate Governance Committee, respectively;
- an additional annual cash retainer of $15,000, $10,000 and $8,000 for service as chairman of the Audit Committee, Compensation Committee and the Nominating and Corporate Governance Committee, respectively (in lieu of the additional cash retainer for committee membership);
- an initial option grant to purchase 24,000 shares of our common stock for each non-employee director who first joins our Board, on the date of initial election or appointment to the Board, vesting over a three-year period following the grant date; and
- an annual option grant to purchase 12,000 shares of our common stock for each non-employee director serving on the Board on the date of our annual stockholder meeting, vesting over the one-year period following the grant date.

Each of the option grants described above will vest and become exercisable subject to the director's continuous service to us, provided that each option will vest in full upon a change in control (as defined in the 2018 Plan). The term of each option will be 10 years, subject to earlier termination as provided in the 2018 Plan, except that the post-termination exercise period will be for 12 months from the date of termination, if such termination is other than for death, disability or cause. The options will be granted under our 2018 Plan, the terms of which are described in more detail above under "—Equity Benefit Plans —2018 Plan."

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the ownership of our common stock as of March 15, 2020 by: (i) each of our directors; (ii) each of our named executive officers; (iii) all of our current executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than 5% of its common stock.

The following table is based upon information supplied by officers, directors and principal stockholders and Schedules 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 17,618,591 shares outstanding on March 15, 2020, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address for the following stockholders is: c/o Equillium, Inc., 2223 Avenida De La Playa, Suite 105, La Jolla, CA 92037.

	Beneficial Ownership	
Beneficial Owner	Number of Shares (#)	Percent of Total (%)
Greater than 5% stockholders		
Biocon SA (1)	2,316,134	13.1%
Victory Capital Management, Inc. (2)	2,233,724	12.7%
Named Executive Officers and Directors		
Daniel M. Bradbury (3)	3,740,120	21.2%
Krishna R. Polu, M.D. (4)	236,341	1.3%
Bruce D. Steel (5)	3.740,120	21.2%
Stephen Connelly, Ph.D. (6)	1,321,125	7.5%
Martha J. Demski (7)	34,799	*
Bala S. Manian (8)	34,799	*
Charles McDermott (9)	34,799	*
Mark Pruzanski (10)	34,799	*
All current executive officers and directors as a group (10 persons) (11)	9,451,427	52.3%

* Less than one percent.

(1) The address of Biocon SA is c/o BDO SA, Rue de l'Avenir 2, 2800 Delémont, Switzerland.

(2) Information is based solely on a Schedule 13G/A filed with the SEC on January 29, 2020 by Victory Capital Management, Inc., or Victory. The Schedule 13G/A indicates that Victory has sole voting power with respect to 2,171,974 shares and sole dispositive power with respect to 2,233,724 shares. The address of Victory is 4900 Tiedeman Rd., 4th floor, Brooklyn, OH 44144.

(3) Consists of (i) 2,969,596 shares of common stock held by BioBrit, of which Mr. Bradbury is the managing member, (ii) 742,399 shares of common stock held by The Bradbury Family 2009 Irrevocable Trust dated September 1, 2009, or the Bradbury Trust and (iii) 28,125 shares of common stock that Mr. Bradbury has a right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(4) Consists of 236,341 shares of common stock that Dr. Polu has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(5) Consists of (i) 48,495 shares of common stock held by Mr. Steel, (ii) 3,232,500 shares of common stock held by Bruce D. Steel, as trustee of the Steel Family Revocable Trust dated June 5, 2002, (iii) 431,000 shares of common stock held by Kevin N. Steel, as trustee of the Sierra Kathleen Steel Trust of January 1, 2005 and (iv) 28,125 shares of common stock that Mr. Steel has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(6) Consists of (i) 1,293,000 shares of common stock held by Dr. Connelly and (ii) 28,125 shares of common stock that Dr. Connelly has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(7) Consists of (i) 23,799 shares of common stock held by the Martha J. Demski Trust Dated October 1, 1994, 14,875 shares of which were subject to a right of repurchase by us as of March 15, 2020 and (ii) 11,000 shares of common stock that Ms. Demski has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(8) Consists of (i) 23,799 shares of common stock held by Dr. Manian, 13,387 shares of which were subject to a right of repurchase by us as of March 15, 2020 and (ii) 11,000 shares of common stock that Dr. Manian has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(9) Consists of (i) 23,799 shares of common stock held by the McDermott Family Trust Dated November 25, 2002, 14,875 shares of which were subject to a right of repurchase by us as of March 15, 2020 and (ii) 11,000 shares of common stock that Mr. McDermott has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(10) Consists of (i) 23,799 shares of common stock held by Dr. Pruzanski, 14,875 shares of which were subject to a right of repurchase by us as of March 15, 2020 and (ii) 11,000 shares of common stock that Dr. Pruzanski has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

(11) Consists of (i) the shares described in Notes (3) through (10) above, (ii) 130,520 shares of common stock held by the Keyes Trust Dated September 10, 2004 and beneficially owned by Jason A. Keyes, our Chief Financial Officer, 77,459 shares of which were subject to a right of repurchase by us as of March 15, 2020, (iii) 21,875 shares of common stock that Mr. Keyes has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options, (iv) 70,810 shares of common stock held by Christine Zedelmayer, our Chief Operating Officer, 28,505 shares of which were subject to a right of repurchase by us as of March 15, 2020 and (v) 51,320 shares of common stock that Mrs. Zedelmayer has the right to acquire from us within 60 days of March 15, 2020 pursuant to the exercise of stock options.

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

RELATED-PERSON TRANSACTIONS POLICY AND PROCEDURES

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds $120,000. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of our common stock, including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our Audit Committee (or, where review by our Audit Committee would be inappropriate, to another independent body of our Board) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our Audit Committee or another independent body of our Board takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

CERTAIN RELATED-PERSON TRANSACTIONS

The following includes a summary of transactions with related persons since January 1, 2018, to which we have been a party and in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years:

Employment Arrangements

We currently have written offer letters with our executive officers. For information about our offer letters with our named executive officers, refer to "Executive Compensation— Agreements with our Named Executive Officers."

Stock Options Granted to Executive Officers and Directors

We have granted stock options to our executive officers and directors. For information about our stock option awards to our named executive officers and our directors, refer to "Executive Compensation—Equity-Based Incentive Awards", "Executive Compensation—Outstanding Equity Awards at Fiscal Year-End" and "Executive Compensation—Director Compensation"

Convertible Promissory Note Financing

From May 2017 to June 2018, we issued and sold to investors convertible promissory notes in the aggregate principal amount of approximately $9.4 million. The convertible promissory notes carried an interest rate of 6% per annum. The participants in this convertible promissory note financing included the following executive officers and members of our Board, or entities affiliated with them.

PARTICIPANTS		AGGREGATE PRINCIPAL AMOUNT OF NOTES
Executive Officers and Directors		
Daniel M. Bradbury	$	512,165 (1)
Bruce D. Steel	$	512,164 (2)

(1) Consists of convertible promissory notes held by (i) BioBrit, in the principal amount of $409,732 (which convertible promissory note was originally issued in May 2017 in principal amount of $400,000 and was amended and restated in October 2017 in principal amount of $409,732, which amount includes accrued interest from May 2017 to October 2017), or the BioBrit Note, and (ii) the Bradbury Trust, in the principal amount of $102,433 (which convertible promissory note was originally issued in May 2017 in principal amount of $100,000 and was amended and restated in October 2017 in principal amount of $102,433, which amount includes accrued interest from May 2017 to October 2017), or the Bradbury Trust Note. Mr. Bradbury is the managing member of BioBrit.

(2) Such convertible promissory note, or the Steel Note, was originally issued in May 2017 in principal amount of $500,000 and was amended and restated in October 2017 in principal amount of $512,164, which amount includes accrued interest from May 2017 to October 2017.

The BioBrit Note, the Bradbury Trust Note and the Steel Note automatically converted in connection with the closing of our initial public offering into an aggregate of 38,796 shares, 9,699 shares and 48,495 shares of our common stock, respectively.

Biocon Agreements

In May 2017, we entered into a collaboration and license agreement, or the Biocon License, and a clinical supply agreement with Biocon SA (subsequently assigned to Biocon Limited), one of our 5% stockholders. In connection with the Biocon License, we entered into a Common Stock Purchase Agreement with Biocon SA, pursuant to which we issued 2,088,074 shares of our common stock as consideration under the Biocon License.

In connection with the closing of our initial public offering, we issued to Biocon SA an additional 228,060 shares of common stock pursuant to certain anti-dilution rights that were satisfied in full upon such issuance.

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may decline in value to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

INDEPENDENCE OF THE BOARD OF DIRECTORS

As required under the Nasdaq Stock Market listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our Board consults with our counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and us, our senior management and our independent auditors, the Board has affirmatively determined that the following four directors are independent directors as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules: Dr. Manian, Mr. McDermott, Ms. Demski and Dr. Pruzanski. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with us. Mr. Bradbury, Dr. Connelly and Mr. Steel are not considered independent because of their current employment with us.

Item 14. Principal Accounting Fees and Services.

PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table represents aggregate fees billed to us by KPMG for the fiscal years ended December 31, 2019 and 2018:

	Fiscal Year Ended December 31, 2019	Fiscal Year EndedDecember 31, 2018
Audit Fees (1)	$ 402,785	$ 638,989
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 402,785	$ 638,989

(1) Audit fees consist of fees billed for professional services by KPMG for audit and quarterly review of our financial statements and review of our registration statements and related issuances of consents, and related services that are normally provided in connection with statutory and regulatory filings or engagements. Included in the 2019 audit fees is $67,785 of fees billed in connection with the filing of our registration statement on Form S-3 in November 2019. Included in the 2018 audit fees is $338,989 of fees billed in connection with our October 2018 public offering.

All fees described above were pre-approved by the Audit Committee.

In connection with the audit of the 2019 financial statements, we entered into an engagement agreement with KPMG that sets forth the terms by which KPMG will perform audit services for us.

PRE-APPROVAL POLICIES AND PROCEDURES

The Audit Committee must pre-approve the audit and non-audit services rendered by our independent registered public accounting firm.

PART IV

Item 15. Exhibits, 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
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.
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+	Equillium, Inc. Non-Employee Director Compensation Policy, as amended, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 12, 2019.
10.6†	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.

10.7†	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.
10.8	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.
10.9+	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.
10.10+	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.
10.11+	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.
10.12+	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.
10.13+	Offer Letter, dated August 1, 2018, by and between the Registrant and Krishna Polu, M.D., incorporated by reference to Exhibit 10.13 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.
10.14	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 September 17, 2018.
10.15*	Second Amendment to Collaboration and License Agreement, dated April 22, 2019, by and between the Registrant and Biocon Limited.
10.16	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.
10.17	Open Market Sales Agreement, dated November 13, 2019, by and between the Registrant and Jefferies LLC, incorporated by reference to Exhibit 1.2 of the Registrant's Registration Statement on Form S-3 (File No. 333-234683), filed with the Securities and Exchange Commission on November 13, 2019.
10.18*††	Third Amendment to Collaboration and License Agreement, dated December 10, 2019, by and between the Registrant and Biocon Limited.
10.19*+	Offer Letter, dated January 19, 2018, by and between the Registrant and Christine Zedelmayer.
10.20*+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Daniel M. Bradbury.
10.21*+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Krishna Polu.
10.22*+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Bruce D. Steel.
10.23*+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Christine Zedelmayer.
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*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Label Linkbase Document

* Filed herewith.

\+ 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 26, 2020

By: /s/ Bruce D. Steel

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

POWER OF ATTORNEY

KNOW ALL 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 26, 2020
/s/ Jason A. Keyes Jason A. Keyes	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 26, 2020
/s/ Daniel M. Bradbury Daniel M. Bradbury	Chairman of the Board of Directors	March 26, 2020
/s/ Stephen Connelly, Ph.D. Stephen Connelly, Ph.D.	Chief Scientific Officer and Member of the Board of Directors	March 26, 2020
/s/ Martha J. Demski Martha J. Demski	Member of the Board of Directors	March 26, 2020
/s/ Bala S. Manian, Ph.D. Bala S. Manian, Ph.D.	Member of the Board of Directors	March 26, 2020
/s/ Charles McDermott Charles McDermott	Member of the Board of Directors	March 26, 2020
/s/ Mark Pruzanski, M.D. Mark Pruzanski, M.D.	Member of the Board of Directors	March 26, 2020

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 its subsidiary (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, 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 26, 2020

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

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 13,219	$ 28,508
Short-term investments	39,924	37,405
Prepaid expenses and other current assets	2,288	1,186
Total current assets	55,431	67,099
Property and equipment, net	93	64
Other assets	15	-
Total assets	$ 55,539	$ 67,163
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,873	$ 1,119
Accrued expenses	2,010	909
Total current liabilities	3,883	2,028
Long-term notes payable	9,681	-
Other non-current liabilities	127	200
Total liabilities	13,691	2,228
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2019 and 2018; 17,425,654 and 17,376,236 shares issued and outstanding as of December 31, 2019 and 2018, respectively	1	1
Additional paid-in capital	82,938	80,441
Accumulated other comprehensive income	21	5
Accumulated deficit	(41,112)	(15,512)
Total stockholders' equity	41,848	64,935
Total liabilities and stockholders' equity	$ 55,539	$ 67,163

See accompanying notes.

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

	Year Ended December 31, 2019	Year Ended December 31, 2018
Operating expenses:		
Research and development	$ 17,640	$ 4,943
General and administrative	9,087	3,672
Total operating expenses	26,727	8,615
Loss from operations	(26,727)	(8,615)
Other income (expense), net:		
Interest expense	(279)	(2,558)
Interest income	1,391	340
Other income, net	15	-
Change in fair value of Biocon anti-dilution right	-	(2,417)
Total other income (expense), net	1,127	(4,635)
Net loss	$ (25,600)	$ (13,250)
Other comprehensive income, net:		
Unrealized gain on available-for-sale securities, net	44	5
Foreign currency translation loss	(28)	-
Total other comprehensive income, net	16	5
Comprehensive loss	$ (25,584)	$ (13,245)
Net loss per share, basic and diluted	$ (1.47)	$ (1.09)
Weighted-average common shares outstanding, basic and diluted	17,378,096	12,190,245

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	10,708,074	$ -	$ 10	$ -	$ (2,262)	$ (2,252)
Issuance of common stock, net of liability	446,171	-	-	-	-	-
Issuance of common stock upon conversion of promissory notes	878,834	-	12,303	-	-	12,303
Issuance of common stock to Biocon pursuant to certain anti-dilution rights	228,060	-	3,193	-	-	3,193
Shares issued for public offering, net of underwriters' fees and $2,123 of offering costs	5,115,097	1	64,475	-	-	64,476
Vesting of restricted stock liability	-	-	18	-	-	18
Stock-based compensation expense	-	-	442		-	442
Comprehensive income	-	-	-	5	-	5
Net loss	-	-	-		(13,250)	(13,250)
Balance at December 31, 2018	17,376,236	$ 1	$ 80,441	$ 5	$ (15,512)	$ 64,935
Issuance of common stock under ATM, net of issuance costs	18,250	-	(206)	-	-	(206)
Issuance of common stock pursuant to employee stock purchase plan	13,321	-	42	-	-	42
Vesting of restricted stock liability	-	-	74	-	-	74
Issuance of common stock warrants	-	-	266	-	-	266
Exercise of stock options	17,847	-	69	-		69
Stock-based compensation expense	-	-	2,252	-	-	2,252
Comprehensive income	-	-	-	16	-	16
Net loss	-	-	-	-	(25,600)	(25,600)
Balance at December 31, 2019	17,425,654	$ 1	$ 82,938	$ 21	$ (41,112)	$ 41,848

See accompanying notes.

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

	Year Ended December 31, 2019	Year Ended December 31, 2018
Operating activities:		
Net loss	$ (25,600)	$ (13,250)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	23	6
Stock-based compensation	2,252	442
Deferred rent	2	1
Non-cash interest expense	-	2,557
Change in fair value of Biocon anti-dilution right	-	2,417
Accretion of discount on investments, net	(382)	-
Amortization of term loan discount and issuance costs	65	-
Other non-cash income and expenses	(20)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,115)	(1,140)
Accounts payable	775	843
Accrued expenses	1,051	598
Net cash used in operating activities	(22,949)	(7,526)
Investing activities:		
Purchases of property and equipment	(74)	(35)
Purchases of short-term investments	(54,619)	(37,399)
Maturities of short-term investments	52,527	-
Net cash used in investing activities	(2,166)	(37,434)
Financing activities:		
Proceeds from public offering of common stock, net of $2,123 issuance costs	-	64,475
Proceeds from issuance of convertible promissory notes, net	-	1,599
Proceeds from issuance of notes payable, net of issuance costs	9,881	-
Proceeds from issuance of common stock under ATM, net of issuance costs	(156)	-
Proceeds from exercise of stock options, including early exercise	69	291
Proceeds from ESPP purchase	42	-
Net cash provided by financing activities	9,836	66,365
Effect of exchange rate changes on cash and cash equivalents	(10)	-
Net (decrease) increase in cash and cash equivalents	(15,289)	21,405
Cash and cash equivalents at beginning of period	28,508	7,103
Cash and cash equivalents at end of period	$ 13,219	$ 28,508
Supplemental cash flow information:		
Cash paid for interest	$ 142	$ -
Fair value of common stock warrants in connection with issuance of notes payable	$ 266	$ -
ATM issuance costs in accrued expenses	$ 50	$ -
Amounts included in accounts payable for purchases of property and equipment	$ 11	$ 33
Conversion of convertible promissory notes into common stock	$ -	$ 12,304
Issuance of common stock to Biocon pursuant to certain anti-dilution rights	$ -	$ 3,193

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 engaged in the research and development of products for severe autoimmune and inflammatory disorders with high unmet medical need.

From inception through December 31, 2019, 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 preclinical research, filing two initial Investigational New Drug applications (INDs), commencing clinical development of the Company's initial product candidate, itolizumab (EQ001), and conducting business development activities. In addition, the Company has a limited operating history, has not generated revenues from its principal operations, and the sales and income potential of its business is unproven.

Liquidity

As of December 31, 2019, the Company had $53.1 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) and 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 will not be for at least the next several years, 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. 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, 2019 will be sufficient to fund operations for at least one year from the date this Annual Report on Form 10-K is filed with the U.S. Securities and Exchange Commission (SEC).

Basis of Presentation

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

Principles of Consolidation

In January 2019, the Company created a wholly-owned subsidiary in Australia with the Company serving as the sole shareholder through the subscription of shares. The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency Translation

The Company's wholly-owned subsidiary in Australia uses their local currency to be their 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 quarter and year-to-date period. 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 and were not material to the Company's consolidated results of operations for the year ended December 31, 2019.

Recent Accounting Pronouncements

In February 2015, the FASB issued ASU 2016-02, Leases (Topic 842), which amends the FASB ASC 840 and creates Topic 842, Leases. The new topic supersedes Topic 840, Leases, and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. For companies that are not emerging growth companies (EGCs), ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. For EGCs, the ASU was to be effective for fiscal years beginning after December 15, 2019. However, in November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326)*, *Derivatives and Hedging (Topic 815)* and *Leases (Topic 842*), *Effective Dates (ASU 2019-10)*, which included a one-year deferral of the effective date of ASU 2016-02 for certain entities. As a result, the ASU is now effective for EGCs for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The Company expects to adopt the new standard in the fourth quarter of 2021 using the modified retrospective method, under which the Company will apply Topic 842 to existing and new leases as of January 1, 2021, but prior periods will not be restated and will continue to be reported under Topic 840 guidance in effect during those periods. The Company anticipates that the adoption will not have a material impact on its consolidated statements of operations and consolidated comprehensive loss or its consolidated statements of cash flows but expects to recognize right-of-use assets and liabilities for lease obligations associated with its operating leases.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments (Topic 230)*. ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice for certain cash receipts and cash payments. The standard is effective for annual reporting periods beginning after December 15, 2018 and interim periods reporting within fiscal years beginning after December 15, 2019. The Company adopted this guidance as of January 1, 2019, which did not have a material effect on the consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820) - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which is designed to improve the effectiveness of disclosures by removing, modifying and adding disclosures related to fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company will adopt this ASU on January 1, 2020. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Significant estimates in the Company's consolidated financial statements relate to clinical trial accruals 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, net includes unrealized gains on short-term investments as well as foreign currency translation losses.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking and savings accounts, and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

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 and clinical trial agreements.

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, or the remaining term of the lease).

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.

Research and Development

Research and development expenses include salaries and related overhead expenses, 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.

Deferred Rent

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company leases. The Company's leases for its facilities provide for fixed increases in minimum annual rental payments. The total amount of rental payments due over the lease terms are being charged to rent expense ratably over the life of the leases. The Company classifies the current and non-current portion of deferred rent as accrued expenses and other non-current liabilities, respectively, on the accompanying consolidated balance sheet.

Biocon Anti-Dilution Right

The Company committed to issue to Biocon SA (together with Biocon Limited, Biocon) additional shares of common stock to maintain Biocon's ownership interest at 19.5% of the diluted Company shares outstanding (as defined in the License Agreements (as defined below)) until the Company received aggregate cumulative gross proceeds from sales of equity securities of $15.0 million (Biocon Anti-Dilution Right). As an obligation existed to issue a variable number of shares and that obligation was not indexed to the Company's common stock, the Biocon Anti-Dilution Right was classified as a liability in the accompanying consolidated balance sheet. The Biocon Anti-Dilution Right was recorded at fair value using the precedent transaction method. The fair value of the Biocon Anti-Dilution Right was re-measured at each financial reporting period with any changes in fair value recognized as a component of other expense (income).

In connection with the Company's initial public offering (IPO) in October 2018, the Company issued to Biocon 228,060 shares of common stock in full satisfaction of the Biocon Anti-Dilution Right and the liability was reclassified to stockholders' equity.

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, 2019	Year Ended December 31, 2018
Common stock options	1,821,093	420,481
Common stock warrants	80,428	-
Total	1,901,521	420,481

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, 2019	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	$ 28,549	$ 28,549	$ -	$ -
Agency securities	5,994	-	5,994	-
Certificates of deposit	5,381	5,381	-	-
Total	$ 39,924	$ 33,930	$ 5,994	$ -

	December 31, 2018	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	$ 29,821	$ 29,821	$ -	$ -
Agency securities	5,659	-	5,659	-
Certificates of deposit	1,925	1,925	-	-
Total	$ 37,405	$ 31,746	$ 5,659	$ -

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 accessible 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 prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. The carrying amount of the Company's notes payable of $9.7 million at December 31, 2019 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. No transfers between levels have occurred during the periods presented.

At December 31, 2019 and 2018, the Company had investments in money market funds of $10.3 million and $12.6 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, 2019 and 2018.

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, 2019					
U.S. treasury securities	1 or less	$ 23,513	$ 6	$ (4)	$ 23,515
U.S. treasury securities	>1 and <5	5,035	-	(1)	5,034
Agency securities	1 or less	5,976	19	(1)	5,994
Certificates of deposit	1 or less	4,131	22	-	4,153
Certificates of deposit	>1 and <5	1,220	8	-	1,228
Total		$ 39,875	$ 55	$ (6)	$ 39,924
December 31, 2018					
U.S. treasury securities	1 or less	$ 29,818	$ 3	$ -	$ 29,821
Agency securities	>1 and <5	5,657	2	-	5,659
Certificates of deposit	>1 and <5	1,925	-	-	1,925
Total		$ 37,400	$ 5	$ -	$ 37,405

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 year ended December 31, 2019, as it is management's intention and ability to hold the securities until a recovery of the cost basis or recovery of fair value. Unrealized gains and losses are included in accumulated other comprehensive loss.

5. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Furniture & fixtures	$ 60	$ 23
Machinery & lab equipment	24	24
Computer equipment	38	23
Less accumulated depreciation and amortization	(29)	(6)
Property and equipment, net	$ 93	$ 64

Depreciation expense related to property and equipment was approximately $23,000 and $6,000 for the years ended December 31, 2019 and 2018, respectively. No material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2019 and 2018.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Accrued payroll and other employee benefits	$ 1,215	$ 560
Clinical studies	442	245
Other accruals	267	96
Preclinical studies	15	8
Accrued interest	71	-
Total accrued expenses	$ 2,010	$ 909

7. 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. 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.

8. 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 can 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 (Term A Loan).

Under the terms of the Loan Agreement, the Company may, at its sole discretion, borrow from the Lenders (i) up to an additional $5.0 million (Term B Loan) upon the Company's achievement of 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 Company's Board of Directors (the Term B Milestone) and (ii) up to an additional $5.0 million (Term C Loan and together with Term A Loan and Term B Loan, the Term Loans) upon the Company's achievement of positive topline data in both the Company's Phase 1b aGVHD trial of itolizumab (EQ001) and the Company's Phase 1b asthma trial of itolizumab (EQ001), supporting a formal decision to advance into Phase 2 development, and as confirmed by the Company's Board of Directors (the Term C Milestone). The Company may draw the Term B Loan during the period commencing on the date of the occurrence of the Term B Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term B Milestone, and (iii) the occurrence of an event of default and may draw the Term C Loan during the period commencing on the date of the occurrence of the Term C Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term C Milestone, and (iii) the occurrence of an event of default.

All of the Term Loans mature on June 1, 2024 (the Maturity Date) and require interest-only payments through June 30, 2021, followed by 36 equal monthly payments of principal and interest; provided that if the Company draws the Term B Loan, the Term Loans will require interest-only payments through December 31, 2021, followed by 30 equal monthly payments of principal and interest. The Term Loans will bear 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%.

The Company will be required to make a final payment of 4.50% of the original principal amount of the Term Loans drawn payable on the earlier of (i) the Maturity Date, (ii) the acceleration of any Term Loans, or (iii) the prepayment of the Term Loans (the Final Payment). The Company may prepay all, but not less than all, of the Term Loans 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 applicable Term Loan prepaid on or before the first anniversary of the applicable funding date, (ii) 2.00% of the principal amount of the applicable Term Loan prepaid between the first and second anniversary of the applicable funding date, and (iii) 1.00% of the principal amount of the applicable 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. If the Company borrows under Term B Loan and/or Term C Loan, upon the funding of Term B Loan and/or Term C Loan, as applicable, the Company will issue to the Lenders additional warrants to purchase shares of the Company's common stock equal to 3.00% of each Term Loan amount divided by the lower of (i) the ten day average closing price of the Company's common stock reported on the Nasdaq Global Market prior to funding or (ii) the closing price of the Company's common stock reported on the Nasdaq Global Market on the day prior to funding. Such lower amount of (i) and (ii) above shall also be the exercise price per share for such warrants. The terms of such warrants would be substantially the same as those contained in the Warrants.

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 Loans of $0.1 million were deferred and are included in the discount to the carrying value of the Term Loans 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 Loans using the effective interest method with an effective interest rate of 10.97%.

The aggregate carrying amounts of the Term Loans are comprised of the following (in thousands):

	December 31, 2019	December 31, 2018
Principal	$ 10,000	$ -
Add: accreted liability for final payment fee	35	-
Less: unamortized discount	(354)	
Total	$ 9,681	$ -

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, 2019, the Company was in compliance with the covenants contained in the Loan Agreement.

Future maturities of the Term Loans, including the Final Payment fee, as of December 31, 2019 are as follows (in thousands):

	December 31, 2019
Year ending December 31, 2020	$ -
Year ending December 31, 2021	1,667
Year ending December 31, 2022	3,333
Year ending December 31, 2023	3,333
Year ending December 31, 2024	2,117
	10,450
Unaccreted balance for Final Payment fee on Term Loans	(415)
Unamortized discounts	(354)
	9,681
Less current portion	-
Noncurrent portion	$ 9,681

9. Stockholders' Equity

During 2017, the Company issued 8,620,000 shares of common stock to founders at a price of $0.00001 per share and 2,088,074 shares of common stock to Biocon as partial consideration for the License Agreements (Note 7). The shares issued to Biocon were valued at $0.005 per share, resulting in $9,689 of research license expense.

On October 16, 2018, the Company completed an IPO, selling 4,670,000 shares of common stock at an offering price of $14.00 per share. The Company received net proceeds of approximately $58.7 million, after deducting underwriting discounts, commissions and offering-related transaction costs.

In connection with the closing of the IPO in October 2018, the Convertible Promissory notes automatically converted into an aggregate of 878,834 shares of the Company's common stock and the Company issued 228,060 shares of common stock to Biocon pursuant to certain anti-dilution rights.

In November 2018, the Company sold an aggregate of 445,097 shares of common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, resulting in additional net proceeds of approximately $5.8 million.

In November 2019, the Company entered into an Open Market Sales Agreement℠ with Jefferies LLC (Jefferies) under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $8.45 million from time to time through Jefferies acting as its sales agent (ATM facility). In December 2019, the Company sold an aggregate of 18,250 shares of its common stock under the ATM facility resulting in net negative proceeds of $0.2 million, after deducting the facility's costs. Subsequent to December 31, 2019, the Company sold an aggregate of 174,649 shares of its common stock under the ATM facility resulting in net proceeds of $0.8 million.

2018 Equity Incentive Plan

In October 2018, the Company adopted the 2018 Equity Incentive Plan (the 2018 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.

Initially, the maximum number of shares of the Company's common stock that may be issued under the 2018 Plan is 2,229,773 shares which consists of 333,119 shares of common stock reserved for issuance under the Company's 2017 Equity Incentive Plan (2017 Plan) at the time the 2018 Plan was adopted, 1,040,000 new shares of common stock approved for issuance under the 2018 Plan and 856,654 shares underlying awards granted under the 2017 Plan that were outstanding as of the effective date of the 2018 Plan and which will be added to the 2018 Plan's reserve if such awards expire or terminate for any reason prior to exercise or settlement, are forfeited because of the failure to meet a contingency or condition required to vest such shares or are reacquired, withheld or not issued to satisfy a tax withholding or to satisfy a purchase price or exercise price of a stock award. As of December 31, 2019, the number of shares reserved under the 2018 Plan was 813,473 shares. 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 Company's board of directors.

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 of Directors 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.

A summary of the Company's stock option activity under its equity incentive plans are as follows:

	Shares Subject to Options	Weighted-Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Options Outstanding at December 31, 2018	420,483	$ 3.75		
Granted	1,502,000	$ 6.12		
Exercised	(17,847)	$ 3.87		
Forfeitures and cancellations	(83,543)	$ 5.05		
Options Outstanding at December 31, 2019	1,821,093	$ 5.64	9.24	$ 17
Options Exercisable at December 31, 2019	367,676	$ 3.75	8.71	$ 17

Aggregate intrinsic value represents the product of the number of options multiplied by the difference between the Company's closing stock price per share on the last trading day of the fiscal period, which was $3.38 as of December 31, 2019, and the exercise price.

The weighted-average fair value per share of options granted for the years ended December 31, 2019 and 2018 were $4.65 and $5.79, respectively.

The following table summarizes certain information regarding stock options (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2018
Fair value of options vested during the period	$ 1,439	$ 46
Cash received from options exercised during the period	$ 69	$ 291
Intrinsic value of options exercised during the period	$ -	$ 3,346

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 Company's board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2).

As of December 31, 2019, the Company had issued 13,321 shares of common stock under the ESPP which were issued during the year ended December 31, 2019. The Company had 503,716 shares available for future issuance under the ESPP as of December 31, 2019.

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, 2019, 265,232 and 446,171 unvested shares issued under early exercise provisions were subject to repurchase by the Company, respectively. The balance sheet reflects an unvested stock liability of $0.2 million and $0.3 million as of December 31, 2019 and 2018, respectively. The short-term portion of the unvested stock liability totals $0.1 million and is classified as accrued expenses on the accompanying consolidated balance sheet. The long-term portion of the unvested stock liability totals $0.1 million and 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, 2019	Year Ended December 31, 2018
Research and development	$ 1,207	$ 251
General and administrative	1,045	191
Total	$ 2,252	$ 442

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, 2019	Year Ended December 31, 2018
Risk-free interest rate	2.23%	2.83%
Expected volatility	93.58%	88.29%
Expected term (in years)	5.77	5.91
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.

Unrecognized compensation expense for stock options at December 31, 2019 was $8.6 million which is expected to be recognized over a weighted-average period of 3.26 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following as of December 31, 2019 and 2018:

	December 31, 2019	December 31, 2018
Stock options issued and outstanding	1,821,093	420,483
Warrants for common stock	80,428	-
Awards available under the 2018 Equity Incentive Plan	813,473	1,363,119
Employee stock purchase plan	503,716	343,275
Total	3,218,710	2,126,877

10. 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 expire in February 2022. The lease for space in South San Francisco expires in February 2021. Rent expense was $0.2 million and $49,000 for the years ended December 31, 2019 and 2018, respectively.

The future minimum lease payments required under non-cancelable leases as of December 31, 2019, are summarized as follows (in thousands):

Years Ended December 31,	
2020	$ 150
2021	74
2022	10
Total	$ 234

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, 2019, there was no litigation against the Company.

11. Income Taxes

The components of loss before income tax provision (benefit) for the years ended December 31, 2019 and 2018 consist of the following (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2018
US	(23,167)	(13,250)
Foreign	(2,433)	-
	$ (25,600)	$ (13,250)

The Company has not recorded a current or deferred tax expense or benefit for the years ended December 31, 2019 and 2018.

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, 2019 and 2018 (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2018
Income taxes at statutory rates	$ (5,376)	$ (2,783)
State income tax, net of federal benefit	1	-
Stock based compensation	276	38
Permanent items	(104)	1,256
Federal research credit	(684)	(222)
Change in federal valuation allowance	5,887	1,711
	$ -	$ -

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, 2019 and 2018 are as follows (in thousands):

	December 31, 2019	December 31, 2018
Deferred tax assets:		
Net operating loss carryforward	$ 7,212	$ 2,268
Credits	1,227	334
Intangibles	129	185
Other	409	224
Total deferred tax assets	8,977	3,011
Valuation allowance	(8,976)	(3,011)
Total deferred tax assets, net of allowance	$ 1	$ -
Deferred tax liabilities:		
Other	(1)	-
Total deferred tax liabilities	$ (1)	$ -
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 $9.0 million as of December 31, 2019 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 $6.0 million during the year ended December 31, 2019.

At December 31, 2019, the Company had federal and California tax loss carry forwards of approximately $28.3 million and $8.2 million, respectively. The federal net operating loss carryover includes $27.5 million of net operating losses generated subsequent to 2017. Federal net operating losses generated after December 31, 2017 carryover indefinitely and may generally be used to offset up to 80% of future 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 $2.7 million of Australian net operating loss carryforwards that are carried forward indefinitely.

At December 31, 2019, the Company had federal and state tax credit carry forwards of approximately $0.6 million and $0.4 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, 2019 and 2018 (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2018
Unrecognized Tax Benefits – Beginning	$ 89	$ 19
Gross increases – tax positions in prior period	-	-
Gross decreases – tax positions in prior period	-	(11)
Gross increase – current-period tax positions	271	81
Gross decrease – current-period tax positions	-	-
Settlements	-	-
Lapse of statute of limitations	-	-
Unrecognized Tax Benefits – Ending	$ 360	$ 89

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 balance sheets as of December 31, 2019 and has not recognized interest and/or penalties in the consolidated statement of operations for the year ended December 31, 2019.

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

12. 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 has not made any contributions for the years ended December 31, 2019 and 2018.

13. Selected Quarterly Financial Data (unaudited)

The following table contains unaudited quarterly financial information for the years ended December 31, 2019 and 2018. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

in thousands (except per share amounts)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2019				
Operating expenses	$ 6,348	$ 6,439	$ 6,324	$ 7,616
Net loss	(5,950)	(6,069)	(6,014)	(7,567)
Net loss per common share, basic and diluted	$ (0.34)	$ (0.35)	$ (0.35)	$ (0.44)
Year Ended December 31, 2018				
Operating expenses	$ 1,037	$ 1,125	$ 2,226	$ 4,228
Net loss	(1,577)	(1,765)	(4,917)	(4,992)
Net loss per common share, basic and diluted	$ (0.15)	$ (0.16)	$ (0.44)	$ (0.31)

14. Subsequent Events

In March 2020, as a result of impacts and risks associated with the current global pandemic caused by COVID-19, the Company decided to pause enrollment of the Company's Phase 1b clinical trial of itolizumab (EQ001) in uncontrolled asthma and the Company's Phase 1b clinical trial of itolizumab (EQ001) in 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 the Company's concern for the well-being of patients and their caregivers. The Company is continuing to enroll 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.

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.

EXHIBIT 4.4

DESCRIPTION OF COMMON STOCK

The following summary description of the common stock of Equillium, Inc. (we, our or us) is based on the provisions of our amended and restated certificate of incorporation, as well as our amended and restated bylaws, and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and the Delaware General Corporation Law. Our amended and restated certificate of incorporation and amended and restated bylaws have previously been filed as exhibits with the Securities and Exchange Commission.

Voting. Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends. Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation. In the event of our liquidation, dissolution or winding-up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL, which generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 of the DGCL defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

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); and
- 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.

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 the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock.

Forum for Disputes

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (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 choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction).

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing on the Nasdaq Global Market

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

Exhibit 10.15

SECOND AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This Second Amendment To Collaboration and License Agreement (***"Amendment"***) is made and entered into effective as of April 22, 2019 (the ***"Amendment Date"*****),** by and between **Equillium, Inc.,** a corporation organized under the laws of the State of Delaware, USA, with its principal office at 2223 Avenida de la Playa, Suite 108, La Jolla, California 92037, USA (***"Equillium"*****),** and **Blocon Limited,** a company incorporated and existing under the laws of India and having its registered office at 20th KM, Hosur Road, Electronics City P.O. Bangalore 560 100, India (***"Biocon"***).

Recitals

Whereas, Equillium and Biocon (as successor-in-interest to Biocon's Affiliate, Biocon SA) are parties to that certain Collaboration and License Agreement dated May 22, 2017 (the ***"Original Agreement"*****),** as amended by that certain First Amendment to Collaboration and License Agreement dated September 28, 2018 (collectively with the Original Agreement, the ***"Agreement"*****);**

Whereas, Equillium desires to expand the Limited Field, and, in recognition of Equillium's achievement of one of the Field Expansion Milestones and its progress to date in developing Product, Biocon is willing to expand the Limited Field, to include lupus and all related Indications; and

Whereas, the parties now wish to amend the Agreement as expressly set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Equillium and Biocon hereby agree as follows:

1. **Defined Terms.** Capitalized terms used but not otherwise defined in this Amendment shall have the meanings provided in the Agreement.

2. **Limited Field.** Section 1.69 of the Original Agreement is hereby amended and restated to read in its entirety as follows:

> **"1.69 "Limited Field"** shall mean the diagnosis, treatment, prevention and palliation of: (a) Orphan Indications; (b) all asthmatic conditions, including, without limitation, the symptoms thereof (which shall collectively be treated as a single Indication for purposes of this Agreement); (c) all lupus diseases, disorders and conditions, including, without limitation, lupus nephritis, systemic lupus erythematosus, cutaneous lupus, and the symptoms of any of the foregoing. By way of clarity, for the purpose of the Agreement, sub section (b) of this Section 1.69 and systemic lupus erythematosus are considered as Indications other than Orphan Indications. Consequently, Section 4.2(b)(iv) of the Original Agreement shall apply to Biocon's obligation to supply ITO finished drug product for use in the conduct of clinical trials of the Product with respect to sub section (b) of this Section 1.69 and systemic lupus erythematosus.

3. **Achievement of First Field Expansion Milestone.** Biocon acknowledges and agrees that Equillium has achieved the Field Expansion Milestones set forth in Section 2.3(a) of the Original Agreement.

4. **Effectiveness of Agreement.** Except as expressly amended by this Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

In Witness Whereof, the parties have duly executed this Second Amendment to Collaboration and License Agreement as of the Amendment Date.

Equillium, Inc.

By: /s/ Daniel M. Bradbury

Name: Daniel M. Bradbury

Title: Chief Executive Officer

Biocon Limited

1. By /s/ Arun Chandavarkar

Name: ARUN CHANDAVARKAR

Title: CEO & JE. MANAGING DIRECTOR

2. By: /s/ Siddharth Mittal

Name: SIDDHARTH MITTAL

Title: PRESIDENT - FINANCE

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE EQUILLIUM, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO EQUILLIUM, INC. IF PUBLICLY DISCLOSED.

Exhibit 10.18

THIRD AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This Third Amendment to Collaboration and License Agreement ("Amendment") is made and entered into effective as of December 10, 2019 (the **"Amendment Date"),** by and between **Equillium, Inc.,** a corporation organized under the laws of the State of Delaware, USA, with its principal office at 2223 Avenida de la Playa, Suite 108, La Jolla, California 92037, USA (**"Equillium"),** and **Biocon Limited,** a company incorporated and existing under the laws of India and having its registered office at 20th KM, Hosur Road, Electronics City P.O. Bangalore 560 100, India (**"Biocon")**.

Recitals

Whereas, Equillium and Biocon (as successor-in-interest to Biocon's Affiliate, Biocon SA) are parties to that certain Collaboration and License Agreement dated May 22, 2017 (the **"Original Agreement"),** as amended by that certain First Amendment to Collaboration and License Agreement dated September 28, 2018, and that certain Second Amendment to Collaboration and License Agreement dated April 22, 2019 (collectively with the Original Agreement, the **"Agreement")**;

Whereas, Equillium and Biocon have entered into a Letter Agreement dated August 28, 2019 (the **"Letter Agreement"),** with respect to certain matters relating to the Biocon Territory as set forth in detail in the Letter Agreement;

Whereas, Equillium desires to expand the Equillium Territory, and, in recognition of Equillium's progress to date in developing Product and in securing funding for such development, Biocon is willing to expand the Equillium Territory, to include Australia and New Zealand; and

Whereas, the parties now wish to amend the Agreement as expressly set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Equillium and Biocon hereby agree as follows:

1. **Defined Terms.** Capitalized terms used but not otherwise defined in this Amendment shall have the meanings provided in the Agreement.

2. **Biocon Territory.** Australia and New Zealand are hereby deleted from Exhibit C to the Original Agreement.

3. **Equillium Territory.** Section 1.41 of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"1.41 "Equillium Territory" shall mean: (a) the US, including its territories and possessions, and Canada (collectively, the **"North American Territory");** and (b) Australia and New Zealand (collectively, the **"AUS/NZ Territory**")."

4. Royalties Payable by Equillium. The table of royalty rates applicable to tiers of aggregate annual Net Sales in the Equillium Territory in Section 5.4(a) of the Original Agreement is hereby replaced with the following tables of (a) royalty rates applicable to tiers of aggregate annual Net Sales by Equillium and its Affiliates and Sublicensees in the North American Territory and (b) royalty rates applicable to tiers of aggregate annual Net Sales by Equillium and its Affiliates (but not by Sublicensees) in the AUS/NZ Territory, respectively:

Tiers of Aggregate Annual Net Sales by Equillium and its Affiliates and Sublicensees in North American Territory	Royalty Rate
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates and Sublicensees in the North American Territory in a calendar year that is less than or equal to $[***] million	[***]%
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates and Sublicensees in the North American Territory in a calendar year that is greater than $[***] million and less than or equal to $[***] billion.	[***]%
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates and Sublicensees in the North American Territory in a calendar year that is greater than $[***] billion and less than or equal to $[***] billion	[***]%
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates and Sublicensees in the North American Territory in a calendar year that is greater than $[***] billion	[***]%

Tiers of Aggregate Annual Net Sales by Equillium and its Affiliates (but not by Sublicensees) in AUS/NZ Territory	Royalty Rate
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates (but not by Sublicensees) in the AUS/NZ Territory in a calendar year that is less than or equal to $[***] million	[***]%
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates (but not by Sublicensees) in the AUS/NZ Territory in a calendar year that is greater than $[***] million and less than or equal to $[***] million	[***]%
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates (but not by Sublicensees) in the AUS/NZ Territory in a calendar year that is greater than $[***] million and less than or equal to $[***] million	[***]%
That portion of aggregate annual Net Sales of Products by Equillium and its Affiliates (but not by Sublicensees) in the AUS/NZ Territory in a calendar year that is greater than $[***] million	[***]%

5. **Sublicensing of AUS/NZ Territory Rights.** In the event that Equillium enters into any agreement granting a Third Party a sublicense under the Equillium License to develop and commercialize ITO and Products in the Field in the AUS/NZ Territory (an **"AUS/NZ Territory Sublicense"),** any upfront payment received by Equillium from the applicable Sublicensee for such AUS/NZ Territory Sublicense under such agreement shall first be used to reimburse Equillium for the documented reasonable out-of-pocket costs, including, without limitation, travel costs and legal fees and costs, incurred by Equillium in the negotiation of such agreement, including the term sheet for such definitive license agreement **("Equillium AUS/NZ Transaction Costs'").** Equillium shall inform Biocon in writing of the amount of such Equillium AUS/NZ Transaction Costs and provide copies of reasonable supporting documentation for such Equillium AUS/NZ Transaction Costs to Biocon. Equillium shall pay to Biocon: (a) [***]% of the remainder of such upfront payment (after reimbursement of Equillium AUS/NZ Transaction Costs) within [***] days after receipt of such upfront payment and determination of the amount of Equillium AUS/NZ Transaction Costs to be deducted therefrom; and (b) [***]% of each other payment received by Equillium from such Sublicensee for the AUS/NZ Territory Sublicense (including, without limitation, royalty payments with respect to Net Sales of Products by such Sublicensee in the AUS/NZ Territory) under such agreement within [***] days after receipt of such payment.

6. **Effectiveness of Agreement.** Except as expressly amended by this Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

7. **Counterparts.** This Amendment may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Amendment may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

[Signature page follows.]

In Witness Whereof, the parties have duly executed this Third Amendment to Collaboration and License Agreement as of the Amendment Date.

Equillium, Inc.		**Biocon Limited**	
By:	/s/ Bruce D. Steel	**1. By:**	/s/ Siddhath Mittal
Name:	Bruce D. Steel	**Name:**	SIDDHATH MITTAL
Title:	President and Chief Business Officer	**Title:**	PRESIDENT - FINANCE
		2. By:	/s/ Kiran Mazumdar - Shaw
		Name:	KIRAN MAZUMDAR - SHAW
		Title:	CHAIR PERSON & MANAGING DIRECTOR.

Exhibit 10.19

Equillium, Inc.

January 19, 2018

Christine Zedelmayer
12463 Rancho Bernardo Rd, Suite 127
San Diego, CA 92128

Re: Employment Terms

Dear Christine:

Equillium, Inc. (the "**Company**") is pleased to offer you the position of Vice President of Operations on the following terms.

You will report to the Chief Executive Officer**.** Your home office will be at our offices located in La Jolla, California, and you may also be required to work at other offices and locations from time to time as required to perform your job duties. The Company may change your position, duties and work location from time to time in its discretion.

The Company's regular business hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt salaried employee, you will be expected to work additional hours, including evenings and weekends, as required to perform your job duties, and you will not be eligible for overtime pay.

Your base salary will be at the annualized rate of $230,000, less required and designated payroll deductions and withholdings, paid semi-monthly.

You will be eligible to earn an annual discretionary performance-based bonus at an annual target amount of thirty percent (30%) of your then current base salary, based on the attainment of individual and Company objectives to be determined and approved by the Company. The Company's payment, and the amount, of any such bonus shall be in the sole discretion of the Company. No amount of bonus is guaranteed, and, in addition to the other conditions for earning any such bonus, you must remain an employee in good standing of the Company on the date the bonus is determined and paid.

Pursuant to the Company's equity incentive plan ("Equity Plan") and subject to approval by the Company's Board of Directors (the "Board"), you will be provided with stock option awards to purchase shares of the Company's common stock (the "Options") equal to 0.5% of the Company's outstanding shares at the time of the Options grant, at the sole discretion of the Board. The Options will have a per share exercise price at no less than the fair market value of the Company's common stock as of the date of grant as determined by the Board, and will be governed in full by the terms and conditions of the Equity Plan and your associated stock option agreements.

You will be eligible to participate in the Company's standard employee benefits (pursuant to the terms and conditions of the benefit plans and applicable policies), as they may be terminated or changed from time to time within the Company's discretion.

As a Company employee, you will be expected to comply with Company policies and procedures, which will be provided to you. As a condition of employment, you must read, sign and comply with the enclosed Employee Confidential Information and Invention Assignment Agreement ("**Confidential Information Agreement**"), which, among other provisions, prohibits any unauthorized use or disclosure of Company proprietary, confidential or trade secret information.

In your work for the Company, you will be prohibited from using or disclosing any confidential, proprietary or trade secret information or other property of any former employer or third party to whom you have an obligation of confidentiality. Rather, you will be required to use only information that is generally known and used by persons with training and experience comparable to your own, is common knowledge in the industry or otherwise legally in the public domain, or is otherwise provided or developed by the Company. You agree that you will not bring onto Company premises or use in your work for the Company any confidential, proprietary or trade secret information or other property belonging to any former employer or third party that you are not authorized to use and disclose. You represent further that you have disclosed to the Company in writing any agreement you may have with any third party (e.g., a former employer) that may limit your ability to perform your duties to the Company, or that could present a conflict of interest with the Company, including but not limited to disclosure (and a copy) of any contractual restrictions on solicitations or competitive activities. By accepting employment with the Company, you are representing that you will be able to perform your job duties within these parameters, and that you are not in unauthorized possession or control of any confidential, proprietary or trade secret information or other property of any former employer or third party.

Your employment relationship with the Company will be at will. You may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time, with or without cause or advance notice. Your employment at-will status can only be changed in a written agreement signed by you and the Board of Directors of the Company.

As required by law, this offer is subject to satisfactory proof of your identity and right to work in the United States. Additionally, this offer is subject to you providing satisfactory professional references to the Company. Further, this offer is conditioned on completion, with results satisfactory to the Company, of a required pre-employment background check. You must timely provide all information and documents required to complete that process.

To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company both agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this letter agreement, your employment with the Company, or the termination of your employment with the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. ("**JAMS**") or its successors by a single arbitrator. The arbitration will be held in San Diego, California, or such other location as then-agreed by the parties. ***Both you and the Company acknowledge that by agreeing to this arbitration procedure, you each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding***. Any such arbitration proceeding will be governed by JAMS' then applicable rules and procedures for employment disputes, which can be found at

http://www.jamsadr.com/rules-clauses/ and which will be provided to you upon request. In any such proceeding, the arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. You and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or you from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those which would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

This letter agreement, together with your Confidential Information Agreement, will form the complete and exclusive statement of your employment agreement with the Company. The terms in this letter agreement supersede any other agreements, promises or representations made to you by anyone, whether oral or written, regarding the subject matters hereof. This letter agreement cannot be changed except in a written agreement signed by you and the Board of Directors of the Company, with the exception of those changes expressly reserved to the Company's discretion in this letter agreement. This letter agreement is governed by the laws of the state of California, without reference to conflicts of law principles. If any provision of this letter agreement shall be held invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect the other provisions of this letter agreement, and such provision will be reformed, construed and enforced so as to render it valid and enforceable consistent with the general intent of the parties insofar as possible under applicable law. With respect to the enforcement of this letter agreement, no waiver of any right hereunder shall be effective unless it is in writing.

Please sign and date this letter and the enclosed Confidential Information Agreement, and return them to me if you decide to accept employment with the Company under the terms described above. If you accept our offer, we would like you to no later than February 1, 2018.

We look forward to your favorable reply and to a productive and enjoyable working relationship. Sincerely,

/s/ Daniel M. Bradbury
Chief Executive Officer

Accepted:

	January 25, 2018
/s/ Christine Zedelmayer	Date

Attachments: Employee Confidential Information and Inventions Assignment Agreement

150708522 v

Exhibit 10.20

EQUILLIUM, INC.

FIRST AMENDMENT TO
OFFER LETTER

This First Amendment to Offer Letter (this "***Amendment***"), amending that certain Offer Letter (the "***Offer Letter***"), dated June 1, 2018, by and between Equillium, Inc. (the "***Company***") and Daniel M. Bradbury (the "***Executive***"), is entered into effective as of January 1, 2020. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Offer Letter.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Offer Letter; and

WHEREAS, the Company and the Executive desire to amend the Offer Letter as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Offer Letter, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. **First Paragraph of the Offer Letter.** The reference to "Chief Executive Officer" contained in first paragraph of the Offer Letter is hereby amended and restated such that it shall be "Executive Chairman."

2. **Second Paragraph of the Offer Letter**. The second paragraph of the Offer Letter is hereby amended and restated in its entirety to read as follows:

> "You will report to the Board of Directors. Your home office will be at our offices located in La Jolla, California, and you may also be required to work at other offices and locations from time to time (including, without limitation, our offices located in South San Francisco, California) as required to perform your job duties. You will maintain access to continued administrative support (by Bethany Heintz). The Company may change your position, duties and work location from time to time in its discretion."

3. **Fourth Paragraph of the Offer Letter.** The reference to "$400,000" contained in fourth paragraph of the Offer Letter is hereby amended and restated such that it shall be "$150,000."

4. **Fifth Paragraph of the Offer Letter.** The fifth paragraph of the Offer Letter is hereby amended and restated in its entirety to read as follows:

"Reserved."

5. **Eighth Paragraph of the Offer Letter.** The reference to "a Deemed Liquidation Event (as defined in the Company's Amended and Restated Certificate of Incorporation, as amended from time to time)" contained in eighth paragraph of the Offer Letter is hereby amended and restated such that it shall be "the effective date of a Change in Control (as defined in the Company's 2018 Equity Incentive Plan)."

6. **Effect of Amendment**. Except as expressly modified by this Amendment, the Offer Letter shall remain unmodified and in full force and effect.

7. **Governing Law**. This Amendment shall be governed by the laws of the State of California, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction.

8. **Counterparts**. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]

In Witness Whereof, the parties have executed this First Amendment to Offer Letter as of the date first written above.

COMPANY:
Equillium, Inc.

By: /s/ Bruce D. Steel

Name: Bruce D. Steel

Title: President and Chief Business Officer

EXECUTIVE:

/s/ Daniel M. Bradbury
Daniel M. Bradbury

216766663 v3

Exhibit 10.21

EQUILLIUM, INC.

FIRST AMENDMENT TO
OFFER LETTER

This First Amendment to Offer Letter (this "***Amendment***"), amending that certain Offer Letter (the "***Offer Letter***"), dated August 1, 2018, by and between Equillium, Inc. (the "***Company***") and Krishna Polu, M.D. (the "***Executive***"), is entered into effective as of January 1, 2020. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Offer Letter.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Offer Letter; and

WHEREAS, the Company and the Executive desire to amend the Offer Letter as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Offer Letter, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. **First Paragraph of the Offer Letter.** The reference to "Chief Medical Officer" contained in first paragraph of the Offer Letter is hereby amended and restated such that it shall be "Executive Vice President Research & Development and Chief Medical Officer."

2. **Fifth Paragraph of the Offer Letter.** The reference to "$375,000" contained in fifth paragraph of the Offer Letter is hereby amended and restated such that it shall be "$450,000."

3. **Sixth Paragraph of the Offer Letter.** The reference to "thirty percent (30%)" contained in sixth paragraph of the Offer Letter is hereby amended and restated such that it shall be "forty percent (40%)."

4. **Ninth Paragraph of the Offer Letter.** The reference to "a Deemed Liquidation Event (as defined in the Company's Amended and Restated Certificate of Incorporation, as amended from time to time)" contained in ninth paragraph of the Offer Letter is hereby amended and restated such that it shall be "the effective date of a Change in Control (as defined in the Company's 2018 Equity Incentive Plan)."

5. **Effect of Amendment**. Except as expressly modified by this Amendment, the Offer Letter shall remain unmodified and in full force and effect.

6. **Governing Law**. This Amendment shall be governed by the laws of the State of California, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction.

7. **Counterparts**. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]

In Witness Whereof, the parties have executed this First Amendment to Offer Letter as of the date first written above.

COMPANY:

Equillium, Inc.

By:/s/ Daniel M. Bradbury

Name: Daniel M. Bradbury

Title: Chief Executive Officer

EXECUTIVE:

/s/ Krishna Polu, M.D.

Krishna Polu, M.D.

216767100 v2

Exhibit 10.22

EQUILLIUM, INC.

FIRST AMENDMENT TO
OFFER LETTER

This First Amendment to Offer Letter (this "***Amendment***"), amending that certain Offer Letter (the "***Offer Letter***"), dated June 1, 2018, by and between Equillium, Inc. (the "***Company***") and Bruce D. Steel (the "***Executive***"), is entered into effective as of January 1, 2020. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Offer Letter.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Offer Letter; and

WHEREAS, the Company and the Executive desire to amend the Offer Letter as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Offer Letter, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. **First Paragraph of the Offer Letter.** The reference to "President and Chief Business Officer" contained in first paragraph of the Offer Letter is hereby amended and restated such that it shall be "President and Chief Executive Officer."

2. **Second Paragraph of the Offer Letter.** The first sentence of the second paragraph of the Offer Letter is hereby amended and restated in its entirety to read as follows:

"You will report to the Board of Directors."

3. **Fourth Paragraph of the Offer Letter.** The reference to "$375,000" contained in fourth paragraph of the Offer Letter is hereby amended and restated such that it shall be "$400,000."

4. **Fifth Paragraph of the Offer Letter.** The reference to "thirty-five percent (35%)" contained in fifth paragraph of the Offer Letter is hereby amended and restated such that it shall be "sixty percent (60%)."

5. **Eighth Paragraph of the Offer Letter.** The reference to "a Deemed Liquidation Event (as defined in the Company's Amended and Restated Certificate of Incorporation, as

amended from time to time)" contained in eighth paragraph of the Offer Letter is hereby amended and restated such that it shall be "the effective date of a Change in Control (as defined in the Company's 2018 Equity Incentive Plan)."

6. **Effect of Amendment**. Except as expressly modified by this Amendment, the Offer Letter shall remain unmodified and in full force and effect.

7. **Governing Law**. This Amendment shall be governed by the laws of the State of California, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction.

8. **Counterparts**. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]

In Witness Whereof, the parties have executed this First Amendment to Offer Letter as of the date first written above.

COMPANY:

Equillium, Inc.

By: /s/ Daniel M. Bradbury

Name: Daniel M. Bradbury

Title: Chief Executive Officer

EXECUTIVE:

/s/ Bruce Steel

Bruce D. Steel

216748496 v2

Exhibit 10.23

EQUILLIUM, INC.

FIRST AMENDMENT TO
OFFER LETTER

This First Amendment to Offer Letter (this "***Amendment***"), amending that certain Offer Letter (the "***Offer Letter***"), dated January 19, 2018, by and between Equillium, Inc. (the "***Company***") and Christine Zedelmayer (the "***Executive***"), is entered into effective as of January 1, 2020. Capitalized terms used herein which are not defined herein shall have the definition ascribed to them in the Offer Letter.

RECITALS

WHEREAS, the Company and the Executive have previously entered into the Offer Letter; and

WHEREAS, the Company and the Executive desire to amend the Offer Letter as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein and in the Offer Letter, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. **First Paragraph of the Offer Letter.** The reference to "Vice President of Operations" contained in first paragraph of the Offer Letter is hereby amended and restated such that it shall be "Senior Vice President and Chief Operating Officer."

2. **Fourth Paragraph of the Offer Letter.** The reference to "$230,000" contained in fourth paragraph of the Offer Letter is hereby amended and restated such that it shall be "$325,000."

3. **Fifth Paragraph of the Offer Letter.** The reference to "thirty percent (30%)" contained in fifth paragraph of the Offer Letter is hereby amended and restated such that it shall be "thirty-seven and one-half percent (37.5%)."

4. **Additional Paragraphs of the Offer Letter.** Three new paragraphs shall be added to the Offer Letter after the seventh paragraph of the Offer Letter which shall read as follows:

> "In the event you are terminated by the Company without Cause (as defined below), you will be eligible to receive an amount equal to your then current Base Salary for six (6) months less required deductions and withholdings and the Company shall pay the premiums for your group

health insurance COBRA continuance coverage for six (6) months following such termination without Cause or, if earlier, until the date on which you become eligible to receive comparable benefits from another employer (the "**Termination Benefits**"). "**Cause**" for termination shall mean that the Company has determined in its sole discretion that you have engaged in any of the following: (i) a material breach of any covenant or condition under the terms of your employment agreement or any other agreement between the parties; (ii) any act constituting dishonesty, insubordination, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) violation of any written Company policy or any act of misconduct; (v) negligence or incompetence in the performance your duties or failure to perform such duties in a manner satisfactory to the Company after the expiration of ten (10) days without cure after written notice of such failure; or (vii) breach of fiduciary duty or the duty of loyalty.

In the event you are terminated by the Company without Cause within one (1) month prior to, or twelve (12) months following, the effective date of a Change in Control (as defined in the Company's 2018 Equity Incentive Plan), you will be eligible to receive an amount equal to your then current Base Salary for twelve (12) months less required deductions and withholdings, an amount equal to your then current Target Bonus less required deductions and withholdings and the Company shall pay the premiums for your group health insurance COBRA continuance coverage for twelve (12) months following such termination without Cause or, if earlier, until the date on which you become eligible to receive comparable benefits from another employer ("**Change of Control Benefits**").

Termination Benefits or Change of Control Benefits, if and when due, shall be paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date (as defined below) with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter. Notwithstanding the foregoing, you shall not receive any of the benefits described in the two paragraphs immediately above unless you deliver to the Company an effective, general release of claims in favor of the Company in the form attached hereto, which has become effective in accordance with its terms (the date that such release can no longer be revoked is referred to as the "**Release Effective Date**"). In no event will you be entitled to both Termination Benefits and Change of Control Benefits. If you are entitled to receive Termination Benefits and thereafter become entitled to Change of Control Benefits, any previously provided Termination Benefits shall offset Change of Control Benefits."

5. **Effect of Amendment**. Except as expressly modified by this Amendment, the Offer Letter shall remain unmodified and in full force and effect.

6. **Governing Law**. This Amendment shall be governed by the laws of the State of California, without regard to any conflicts of law principals thereof that would call for the application of the laws of any other jurisdiction.

7. **Counterparts**. This Amendment may be executed via facsimile or electronic (i.e., PDF) transmission and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[Remainder of Page Intentionally Left Blank]

In Witness Whereof, the parties have executed this First Amendment to Offer Letter as of the date first written above.

COMPANY:

Equillium, Inc.

By: /s/ Daniel M. Bradbury

Name: Daniel M. Bradbury

Title: Chief Executive Officer

EXECUTIVE:

/c/ Christine Zedelmayer
Christine Zedelmayer

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Exhibit 21.1

SUBSIDIARIES OF EQUILLIUM, INC.

Name of Subsidiary	Jurisdiction of Incorporation
Equillium AUS Pty Ltd.	Australia

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. 333-230536) on Form S-8 and (No. 333-234683) on Form S-3 of Equillium, Inc. of our report dated March 26, 2020, with respect to the consolidated balance sheets of Equillium, Inc. as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes, which report appears in the December 31, 2019 annual report on Form 10-K of Equillium, Inc..

/s/ KPMG LLP

San Diego, California
March 26, 2020

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 26, 2020

/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 26, 2020

/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, 2019, 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 26, 2020

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

Date: March 26, 2020

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), irrespective of any general incorporation language contained in such filing.