Annual Report | 2025

Equillium is a biotechnology innovator developing novel therapies to treat severe autoimmune and inflammatory disorders with the mission to develop life-changing therapeutics for patients.

For more information, visit **equilliumbio.com**.

Dear Equillium Stockholders,

2025 was a transformative year for Equillium as we strengthened our balance sheet, sharpened our strategic focus, and positioned the Company to advance EQ504 with greater speed and capital efficiency.

In addition to our August 2025 financing of up to $50 million, led by blue-chip biotechnology investors including Janus Henderson Investors and ADAR1 Capital Management, we further strengthened our financial position in March 2026, completing a $35 million financing with RA Capital Management. In aggregate with this capital, we have meaningfully enhanced our ability to advance EQ504 through key clinical milestones, and we expect to be able to fund operations into 2029. We believe this financing represents strong external validation of our strategy and positions Equillium to execute from a place of greater strength and focus.

Most notably, we centered the organization around EQ504, our novel aryl hydrocarbon receptor (AhR) modulator, which we believe has the potential to become a differentiated, first-in-class oral therapy initially in ulcerative colitis, with broader opportunities across gastrointestinal and inflammatory lung diseases. EQ504's multi-modal, non-immunosuppressive mechanism is designed to address significant unmet needs in inflammatory disease by promoting anti-inflammatory cytokines and epithelial barrier function, and helping restore immune homeostasis. We look forward to initiating our Phase 1 proof-of-mechanism study in mid-2026, with data expected approximately six months thereafter. We believe this study will represent an important milestone for Equillium and a meaningful step forward in demonstrating the clinical potential of EQ504.

We will also be further evaluating opportunities to advance EQ302, our orally available bi-specific inhibitor of IL-15 and IL-21, which we believe may provide significant benefit across a range of gastrointestinal disorders, including celiac disease.

I would like to sincerely thank our employees, partners, investigators, and the patients who participate in clinical research, all of whom are essential to Equillium's progress. I also want to thank our stockholders for your continued support and confidence as we work to advance novel therapies for patients with severe autoimmune and inflammatory disorders.

Our best regards,

Bruce Steel
Chief Executive Officer, Equillium

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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, 2025

OR

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

Commission File Number 001-38692

EQUILLIUM, INC.

(Exact name of registrant as specified in its Charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $7.1 million based on the closing price of the registrant's common stock on June 30, 2025 of $0.32 per share, as reported by the Nasdaq Capital Market. Shares of the registrant's common stock held by executive officers, directors and registrant's affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 20, 2026, there were 63,226,556 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement for its 2026 annual meeting of stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2025. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Auditor Firm Id: 173 Auditor Name: Crowe LLP Auditor Location: Costa Mesa, California, United States

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management's beliefs, opinions and views with respect to future events and are based on estimates, assumptions and information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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

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

RISK FACTORS SUMMARY

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

- We have incurred significant losses since our inception, expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability;
- We will require substantial additional funding to complete the planned or future development and any commercialization of EQ504, EQ302 and any future product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations;
- Raising additional equity capital may cause dilution to our stockholders, and raising additional equity or debt capital may restrict our operations or require us to relinquish rights to our technologies or product candidates;
- We are highly dependent on the successful planned or future development of our current product candidates, EQ504 and EQ302, and we may not be able to obtain regulatory or marketing approval of, or successfully commercialize, these product candidates in any of the indications for which we plan to develop them;
- Any delays in the commencement and completion, or any termination or suspension, of our planned or future clinical studies could result in increased costs to us, and delay or limit our ability to raise capital or generate revenue and adversely affect our commercial prospects;
- Interim, topline or preliminary data from our planned or future clinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- We currently have no marketing and sales organization and have no experience as a company in commercializing products and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with contracted third parties to market and sell any of our products if and when approved, we may not be able to generate product revenue;
- The manufacture of pharmaceutical products is complex and we may encounter difficulties in production, distribution and delivery of our product candidates. If CMOs encounter such difficulties, our ability to provide supply of our product candidates for our planned or future clinical studies, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, if approved, could be delayed or stopped;
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects;
- We rely, and intend to continue to rely, on CROs to conduct our planned or future clinical studies and perform some of our planned or future research and nonclinical 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;

- 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 our product candidates, and we may not be able to compete effectively in our market;
- Even if our product candidates receive marketing approval in any indication, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success; and
- We have in the past and may in the future fail to maintain compliance with the listing requirements of the Nasdaq Capital Market, and as a result, our common stock may be delisted from the Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it difficult for you to sell your shares.

PART I

Item 1. Business.

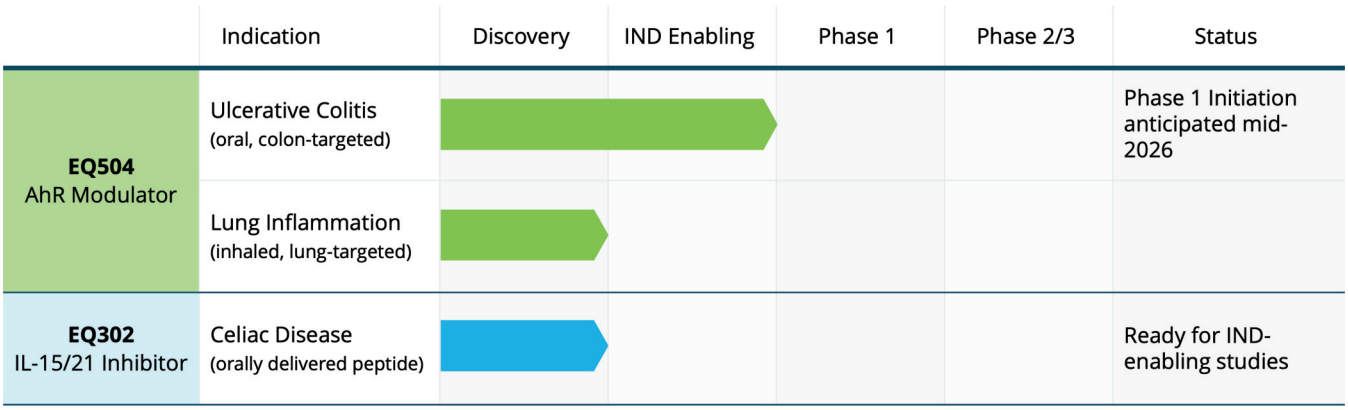
Overview

We are a biotechnology innovator developing novel therapies to treat severe autoimmune and inflammatory disorders with the mission to develop life-changing therapeutics for patients. Our primary goal is to advance EQ504, a novel aryl hydrocarbon receptor, or AhR, modulator, into and through clinical development.

EQ504 is a preclinical-stage, novel AhR modulator that in multiple translational models has been shown to have a therapeutically beneficial impact inducing anti-inflammatory cells and cytokines while reducing proinflammatory cells and cytokines and improving intestinal tissue barrier function and repair. We initially intend to develop EQ504 for the treatment of ulcerative colitis, or UC, and other gastrointestinal, or GI, diseases with potential indication expansion opportunities for the treatment of inflammatory lung diseases.

EQ302 is a preclinical-stage, first-in-class, selective, bi-specific inhibitor of IL-15 and IL-21 formulated for oral delivery. Inhibiting IL-15 and IL-21 is believed to be an effective treatment approach for certain GI indications, including celiac disease. We have conducted preclinical development of EQ302, including in vivo pharmacology studies and formulation development, to further characterize and optimize the product candidate. We are evaluating further advancement of EQ302, including product manufacturing and toxicology studies capable of supporting a potential investigational new drug, or IND, filing and a first-in-human clinical study.

Our novel and differentiated pipeline of therapeutic candidates has the potential to address unmet medical needs in numerous areas, including gastroenterology, dermatology and pulmonology.



Strategy

Our primary 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:

- **Complete the preclinical and clinical development of EQ504.** We intend to commence a Phase 1 proof-of-mechanism study for EQ504 in mid-2026, with data expected to follow approximately six months thereafter. Modulation of AhR has been shown to have a beneficial impact on tissue barrier function, inflammation, cell development and tumor suppression. We initially intend to develop EQ504 for the treatment of UC and other GI diseases with potential indication expansion opportunities for the treatment of inflammatory lung diseases.
- **Evaluate further advancement of EQ302.** Published research has demonstrated the synergistic effect of inhibiting both IL-15 and IL-21 as a therapeutic approach for celiac disease and potentially other autoimmune disorders. Preclinical and translational data has shown that EQ302 is a potent inhibitor of those two cytokines and is stable and permeable in the gut. We are evaluating further advancement of EQ302, including product manufacturing and toxicology studies capable of supporting a potential IND filing and a first-in-human clinical study. Based on the unique mechanism of action of EQ302 and its product profile, including the advantage of oral delivery, we believe that EQ302 has the potential to be an attractive therapeutic option for GI diseases, such as inflammatory bowel disease and celiac disease.
- **Opportunistically expand our pipeline.** We will continue to conduct preclinical and translational studies and assimilate learnings from clinical studies to help inform the selection of additional indications for future development of our product candidates. We will also leverage the collective talent within our organization to

opportunistically discover, acquire or in-license other high-value therapeutic programs that may complement our core strategy or have the potential for synergistic therapeutic benefit in combination with our pipeline assets.

Acquisitions

Acquisitions of innovative technologies and products have played an important role in the growth of our company, and we may continue to evaluate and potentially complete acquisitions in the future.

In October 2024, we acquired Ariagen, Inc., or Ariagen, to obtain exclusive, worldwide rights to EQ504, a potent and selective AhR modulator. Pursuant to the stock purchase agreement with Ariagen, its stockholders and securityholder representative, we are obligated to potentially pay up to a maximum of $55.0 million in the aggregate across the first three regulatory approvals.

We also acquired the exclusive worldwide rights to EQ302, a proprietary platform for discovering additional, novel multi-cytokine targeting product candidates through the acquisition of Bioniz Therapeutics, Inc., or Bioniz, in February 2022. Pursuant to the merger agreement with Bioniz, we are obligated to potentially pay up to $57.5 million in regulatory approval milestones, of which $52.5 million relates to assets acquired that are no longer being pursued and $5 million relates to EQ302.

August Securities Purchase Agreement

On August 10, 2025, we entered into a Securities Purchase Agreement, the Purchase Agreement, with certain institutional and accredited investors, the Investors, pursuant to which we agreed to sell and issue shares of our common stock, par value $0.0001, and pre-funded warrants to purchase shares of common stock, in up to two closings in a private placement transaction, the Private Placement. The initial closing of the Private Placement occurred on August 12, 2025, the Initial Closing. At the Initial Closing, we issued and sold 21,814,874 shares at a purchase price of $0.57 per share and pre-funded warrants to purchase up to 30,816,705 shares at a purchase price of $0.5699 per warrant share, the Warrant Price, to the Investors for gross proceeds to us of approximately $30.0 million. The Purchase Agreement also provides for a potential second closing for up to approximately $20.0 million in gross proceeds in exchange for up to approximately 35,087,717 shares of common stock, subject to achieving certain specified milestones related to clinical study initiation and stock price conditions or waiver thereof.

March Securities Purchase Agreement

On March 11, 2026, we entered into a Securities Purchase Agreement, the March Purchase Agreement, with a certain institutional and accredited investor, the March Investor, pursuant to which we agreed to sell and issue shares of our common stock, par value $0.0001, and a pre-funded warrant to purchase shares of common stock, the March Private Placement. The closing of the Private Placement occurred on March 13, 2026. At the Closing, we issued and sold 1,179,508 shares at a purchase price of $1.854 per share and a pre-funded warrant to purchase up to 17,698,593 shares at a purchase price of $1.8539 per warrant share, the March Warrant Price, to the March Investor for gross proceeds to us of approximately $35.0 million.

We intend to use the net proceeds from the Private Placement and the March Private Placement to fund the further development of EQ504, working capital, and general corporate purposes.

We believe that our cash and cash equivalents will be sufficient to fund our operating expenses into 2029.

EQ504 Product Development

EQ504 is a potent and selective AhR modulator designed with a multi-modal, non-immunosuppressive mechanism of action to be complementary to other inflammation and immunology agents. EQ504 is an investigational therapeutic program with potential for targeted, local delivery via enteric coating for the treatment of UC and other GI diseases or inhaled formulations for the treatment of inflammatory lung diseases.

Ulcerative Colitis Market Overview

UC is a chronic, relapsing inflammatory bowel disease characterized by continuous mucosal inflammation of the colon, most commonly affecting the rectum and extending proximally in a contiguous pattern. UC arises from a dysregulated immune response to intestinal microbiota in genetically predisposed individuals, with environmental, epithelial barrier, and immunologic factors all contributing to disease initiation and progression. UC affects a substantial patient population and the treatment landscape includes multiple biologic and targeted therapies. In 2023, approximately 800,000 patients were treated for UC in the U.S., representing an estimated U.S. total addressable market of approximately $12 billion by 2030. Despite meaningful therapeutic advances over the last decade, including greater than 15 approved therapies, UC continues to impose a substantial burden of illness with remission rates below 30% and mucosal healing a major clinical priority.

Given the chronic nature of UC, its increasing prevalence, and the limitations of existing therapies, there remains a significant opportunity for safe and effective locally-acting agents to expand therapeutic options capable of achieving sustained mucosal healing, improving long‑term outcomes, and reducing reliance on systemic immunosuppression. There remains a gap for therapies that promote mucosal healing and restore gut homeostasis. Novel therapeutic approaches or combination therapies that more precisely modulate immune pathways and restore epithelial barrier integrity have the potential to meaningfully advance the standard of care for patients living with UC.

Rationale for EQ504 for the Treatment of Ulcerative Colitis

EQ504 is an investigational, potent and selective AhR modulator designed with a multi-modal, non-immunosuppressive mechanism of action to be complementary to other inflammation and immunology agents. The AhR signaling pathway plays a critical role in maintaining and regulating barrier function, particularly in tissues such as skin, gut, lung, and eye. AhR is highly expressed in these tissues, and its modulation leads to induction of the pathways that promote barrier tissue function, repair and regeneration. AhR signaling also modulates the activity of key immune cells that induce the production of anti-inflammatory and tissue protective cytokines IL-10 and IL-22. Modulation of AhR supports gut immune homeostasis and protects the mucosal epithelial barrier.

Modulation of AhR has been clinically validated in skin and GI disease. For example, VTAMA (tapinarof) has been FDA-approved for psoriasis and in atopic dermatitis. Also, high levels of clinical remission have been observed in UC patients when treated with *indigo naturalis*. (Naganuma et al., Japanese Society of Gastroenterology 2018, Saiki et al. BMJ Open Gastroenterology 2021, Ben-Horin, et al., Clinical Gastroenterology and Hepatology 2024). EQ504 mitigates disease pathology in the DSS mouse model of colitis, the most widely used *in vivo* model for UC. Specifically, EQ504 protects the intestinal mucosal barrier, blocks inflammatory and histopathological changes, and induces anti-inflammatory cytokines in the colon tissue. EQ504 rescued the mice using a clinically relevant dose and had similar outcomes to a strong immunosuppressant, cyclosporin, and another AhR modulator, indirubin, a component of *indigo naturalis*.

EQ504 Development Plan in Ulcerative Colitis

We initially intend to develop EQ504 for the treatment of UC and other GI diseases with potential indication expansion opportunities for the treatment of inflammatory lung diseases. We intend to commence a Phase 1 healthy volunteer single ascending dose / multiple ascending dose study for EQ504 in mid-2026, to be followed by a Phase 1b/2 study in patients with UC.

EQ302 Product Development

EQ302 is a first-in-class, orally delivered, selective inhibitor of IL-15 and IL-21 and is both stable and permeable in the gut.

Translational and preclinical data support its potential use as a treatment for various GI diseases including celiac disease, an immune disorder related to gluten exposure. The high degree of selectivity for IL-15 and IL-21 inhibition aligns well with the demonstrated key involvement of these two cytokines that work synergistically in driving the pathology in celiac disease and other inflammatory gut and hepatic disorders. EQ302 uses validated hydrocarbon staple technology to stabilize the peptide while retaining its specificity and enabling an attractive drug product profile.

Celiac Disease Market Overview

Celiac disease is a chronic inflammatory intestinal disorder caused by inappropriate cellular and humoral immune responses to the dietary intake of gluten in the genetically susceptible individual. Celiac disease is one of the most common autoimmune disorders, with a reported prevalence of 0.5% to 1% of the global population and affecting approximately 2.3 million people in the United States. The prevalence of celiac disease has increased over the past 50 years, and the rate of diagnosis has risen over the past two decades. Although celiac disease can occur at any age, onset most commonly occurs either in the first two years of life or in the second or third decades of life. Celiac disease occurs selectively in individuals expressing the gene human leukocyte antigen (HLA)-DQ2 or HLA-DQ8. In celiac disease, a mucosal inflammatory response in the intestinal epithelia leads to villous atrophy, and crypt cell hyperplasia. The loss of mucosal integrity in celiac disease is associated with a high burden of illness resulting from a plethora of intestinal and extraintestinal disease manifestations. Currently, there are no approved products to treat celiac disease, and strict adherence to a gluten-free diet is currently the only approach for patients to manage the disease. A full recovery is often observed in pediatric celiac disease patients, but over 40% of adult celiac disease patients maintain histological abnormalities, such as villous structural damage, following complete removal of dietary gluten. Further complicating the gluten-free treatment strategy, 5% of adult patients can develop a refractory form of celiac disease, characterized by severe villous atrophy and the presence of abnormal intraepithelial

lymphocytes, or IELs. This is considered the early stages of enteropathy associated T cell lymphoma, a potentially lethal condition not confined to intestinal epithelia.

Rationale for EQ302 for the Treatment of Celiac Disease

IL-15 has been identified as a key driver of celiac disease pathogenesis. IL-15 is chronically upregulated in the lamina propria and epithelium of the small intestine and directly correlates with the severity of mucosal damage. This proinflammatory cytokine acts on distinct cell types resulting in malfunction of multiple immune mechanisms. Elevated IL-15 in the intestinal lamina propria has been shown to promote phenotypic changes to tolerogenic dendritic cells leading to a decrease in the generation of regulatory T cells, or T_{regs}, a lymphocyte subset critical for maintaining tolerance to self-antigens and promoting tolerance to innocuous dietary antigens. The reduction of inducible T_{regs} to dietary antigens elevates the potential for an intestinal inflammatory immune response to gluten intake. IL‑15 expression is also correlated with the upregulation of the activating NKG2D receptor on cytotoxic lymphocytes and its associated cytotoxic pathway, and with the complementary major histocompatibility complex class I chain-related (MIC) ligands (i.e., MICA and MICB) at the epithelial cell surface that triggers their subsequent killing by cytotoxic lymphocytes.

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

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

EQ302 Development Plan in Celiac Disease

We have conducted preclinical development of EQ302, including *in vivo* pharmacology studies and formulation development, to further characterize and optimize the product candidate. We are evaluating further advancement of EQ302, including product manufacturing and toxicology studies capable of supporting a potential IND filing and a first-in-human clinical study.

Intellectual Property

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

As of March 15, 2026, through our acquisition of Ariagen, we wholly own a patent portfolio directed to selective AhR modulators. This wing of our portfolio includes 4 patent families, including those related to chemical components, technologies related to chemical synthesis, and methods for utilizing this AhR modulator class of molecules.

Of these four AhR modulator patent application families, the first family includes claims covering a chemical class of AhR modulators and methods of using such molecules, with disclosure covering chemical synthesis approaches. This family includes one issued U.S. patent, one issued Korean patent, and one issued Hong Kong patent. The U.S. and Korean patents in this patent family are set to expire in 2037, and the Hong Kong patent is set to expire in 2039.

The second patent application family includes claims covering an indole chemical class of AhR modulators and methods of using such molecules, with disclosure covering chemical synthesis approaches and physico-chemical characteristics. This family includes three issued U.S. patents with one issued U.S. patent set to expire in 2038, and the remaining two issued U.S. patents set to expire in 2040.

The third patent application family includes claims covering a chiral indole chemical class of AhR modulators including EQ504 and methods of using such molecules, with disclosure covering chemical synthesis and physico-chemical characteristics. This family currently includes one issued U.S. patent, one issued Japanese patent, one issued Indian patent, one issued Mexican patent, and one issued New Zealand patent. Also pending are applications in Canada and Israel. If granted, any patents in this patent family are expected to expire in 2040, absent any patent term adjustments or extensions.

The fourth patent application family in preparation will include claims covering EQ504 salt polymorphic forms and formulations, with PCT application filing planned within the next fiscal year. If granted, any patents in this family are expected to expire in 2046 to 2047, absent any patent term adjustments or extensions.

As of March 15, 2026, through our acquisition of Bioniz, we wholly own a patent portfolio directed to composite peptide antagonists. This wing of our portfolio includes four additional patent application families, including those related to the IL-2, IL-9, IL-15 peptide antagonist EQ101, the IL-15 and IL-21 peptide antagonist EQ302, other peptide sequences, and other related technologies for peptide modulation of multi-cytokine signaling largely in the γc-cytokine family space.

Of these four composite peptide patent application families, the first family includes claims currently directed to composite peptides covering EQ101, methods of designing such peptides, and methods of using such peptides to treat various T cell mediated diseases and disorders (including but not limited to RA, immune-mediated hair loss, and myositis). This family includes seven issued U.S patents, one issued Brazilian patent, one issued Hong Kong patent, and one issued Japanese patent. Patents in this patent family are expected to expire in 2032, absent any patent term adjustments or extensions.

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

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

The fourth patent application family includes claims currently directed to EQ101 for use in methods of treating various cytokine storm related disorders. This family includes pending applications in the United States, Canada, China, Hong Kong, Japan, and Korea. If granted, any patents in this patent family are expected to expire in 2041, absent any patent term adjustments or extensions.

We file U.S. provisional patent applications as well as U.S. non-provisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the 153 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not

issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of 2½ years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first 2½ years of filing.

We intend to prosecute the pending applications that we own and in-license and to pursue patent issuance and protection in key commercial markets where we expect significant product sales may occur. We will evaluate on an ongoing basis the patents and applications that came to Equillium with the acquisition of Bioniz and seek to realize cost savings as appropriate.

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

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

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

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

circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Competition

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

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

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We expect to manage sales, marketing, patient access and distribution either through internal resources or through third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We rely on third-party contract manufacturing organizations, or CMOs, for all our required raw materials, drug substance and drug product needs for nonclinical research and clinical trial supply needs.

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

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of drugs such as those we are developing. We, along with third-party contractors, will be required to navigate the various nonclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA and its implementing regulations. The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical studies may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the study is commenced;
- performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed drug product candidate for its intended purpose;
- preparation of and submission to the FDA of a New Drug Application, or NDA, for product candidates like EQ504 and EQ302 that are manufactured through chemical synthesis, after completion of all pivotal clinical studies that includes substantial evidence of safety and efficacy from results of nonclinical testing and clinical studies;
- a determination by the FDA within 60 days of its receipt of a NDA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current good manufacturing practice, or cGMP and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

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

Clinical studies involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical study conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical study must review and approve the plan for any clinical study and its informed consent form before the clinical study begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical study at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the study is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical study if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical study results to public registries.

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

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

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

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

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical studies after a product is approved to gain more information about the product. These so-called Phase 4 clinical study may be made a condition to approval of the NDA. Concurrent with clinical studies, companies may complete additional animal studies and develop additional information about the drug 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. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Submission, Review and Approval of an NDA

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

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

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

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

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

Expedited Development and Review Programs

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

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

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

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

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

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

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 NDA. 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 drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. 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.

Generic Competition and Exclusivity for Small Molecules and Peptides

Small-molecule drugs and certain peptide products are regulated under the Federal Food, Drug, and Cosmetic Act and the Hatch-Waxman Act, which provide an abbreviated pathway for the approval of generic drugs through Abbreviated New Drug Applications, or ANDAs. ANDA applicants rely on the FDA's prior findings of safety and effectiveness for the reference listed drug and must demonstrate pharmaceutical equivalence and bioequivalence, generally without the need for independent clinical trials unless required to support bioequivalence or address product-specific issues.

The Hatch-Waxman framework provides periods of regulatory exclusivity that may restrict the submission or approval of ANDAs. New chemical entities may be eligible for a five-year period of exclusivity, during which the FDA may not accept an ANDA referencing the product, subject to a limited four-year exception for applications containing a Paragraph IV certification. Products supported by new clinical investigations essential to approval may qualify for three-year exclusivity, which limits approval of competing applications that rely on the protected data.

ANDA applicants must also certify to patents listed in the FDA's Orange Book for the reference product. A Paragraph IV certification may lead to patent litigation, which can result in a statutory 30-month stay of FDA approval. In addition, the

regulatory treatment of certain peptide products continues to evolve, as the FDA refines the boundary between products regulated as small molecules and those regulated as biologics. As a result, applicable exclusivity periods and approval pathways for peptide products may change over time.

The Hatch‑Waxman Act and related FDA policies remain the subject of ongoing legislative, regulatory and judicial activity. Accordingly, the timing and potential impact of generic competition for our small‑molecule and peptide product candidates are subject to significant uncertainty.

Other U.S. Healthcare Laws and Compliance Requirements

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

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

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act, or ACA, 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 ACA 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 ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

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

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

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

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

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

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

Coverage, Pricing and Reimbursement

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

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

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

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

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

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

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

Healthcare Reform

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

The ACA has substantially changed healthcare financing and delivery by both governmental and private insurers. There have been amendments and legal and political challenges to certain aspects of the ACA. For example, on August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Additionally, on July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

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

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of two percent per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the IRA, among other things, (1) directs HHS to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least seven years and biologics that have been on the market for at least eleven years covered under Medicare, or the Medicare Drug Price Negotiation Program, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, which took effect in January 2026. Each year thereafter, more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform (TrumpRx) U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again, or MAHA, Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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

Additionally, in the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality, and expand access to care, particularly in light of the recent U.S. Presidential and Congressional elections. These reform initiatives may, among other things, result in modifications to the aforementioned laws and/or the implementation of new laws affecting the healthcare industry.

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.

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, 2025, we employed 14 employees, of which 13 were full-time employees, who were engaged in research and development activities, operations, finance, business development or administration. We also engage temporary employees and consultants as needed.

Corporate Information

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

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

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

Item 1A. Risk Factors.

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biotechnology company incorporated in March 2017 and our operations, to date, have consisted primarily of organizing and staffing our company, business planning, raising capital, in-licensing product rights, conducting clinical and preclinical development, filing INDs, conducting CMC and formulation development activities, conducting business development activities and the general and administrative activities associated with being a public company. We have never completed the development of any product candidate through to marketing approval, and we have never generated any revenue from sales of an approved product. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues from sales of an approved product, and we cannot estimate with precision the extent of our future losses. For the years ended December 31, 2025 and 2024, our net losses were $22.4 million and $8.1 million, respectively. As of December 31, 2025, we had an accumulated deficit of $216.2 million. We expect to incur operating losses for the foreseeable future as we execute our plan to perform research and development activities, conduct preclinical and clinical studies on EQ504 and potentially other product candidates, potentially perform discovery research, conduct formulation development of our product candidates, potentially expand the indications for which we conduct clinical development of our product candidates, potentially acquire or develop new products and/or product candidates, seek regulatory approvals of and potentially commercialize any approved products, hire and retain additional personnel, maintain compliance with regulatory requirements, protect our intellectual property, and manage the administrative aspects of our business. Furthermore, strategic transactions have and may in the future accelerate the rate at which our operating losses increase, including as a result of preclinical, clinical and regulatory expenses incurred to advance our potential product candidates. In addition, if we obtain regulatory approval of any of our product candidates, we expect to incur increased sales and marketing expenses, with certain of such investments potentially being made in advance of an approval. As a result, we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

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

and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding to complete the planned or future development and any commercialization of EQ504, EQ302 and any future product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.

We expect our expenses to potentially increase substantially over the next few years if EQ504 or other product candidates successfully advance through additional stages of development which may include larger, more expensive clinical studies. The development of biotechnology product candidates is capital intensive. As we conduct nonclinical research and clinical development of our product candidates, we will need substantial additional funds to maintain and expand our capabilities in a variety of areas including discovery and nonclinical research, clinical development, regulatory affairs, product development, product quality assurance, and pharmacovigilance. In addition, if we obtain marketing approval of any of our product candidates, we expect to incur significant commercialization expenses for marketing, sales, manufacturing and distribution. Some of those commercialization investments may be made at-risk in advance of receiving an approval.

On August 10, 2025, we entered into a Securities Purchase Agreement, the Purchase Agreement, with certain institutional and accredited investors, the Investors, pursuant to which we agreed to sell and issue shares of our common stock, par value $0.0001, and pre-funded warrants to purchase shares of common stock, in up to two closings in a private placement transaction, the Private Placement. The initial closing of the Private Placement occurred on August 12, 2025, the Initial Closing. At the Initial Closing, we issued and sold 21,814,874 shares at a purchase price of $0.57 per share and pre-funded warrants to purchase up to 30,816,705 shares at a purchase price of $0.5699 per warrant share, the Warrant Price, to the Investors for gross proceeds to us of approximately $30.0 million. The Purchase Agreement also provides for a potential second closing for up to approximately $20.0 million in gross proceeds in exchange for up to approximately 35,087,717 shares of common stock, subject to achieving certain specified milestones related to clinical study initiation and stock price conditions or waiver thereof.

On March 11, 2026, we entered into a Securities Purchase Agreement, the March Purchase Agreement, with a certain institutional and accredited investor, the March Investor, pursuant to which we agreed to sell and issue shares of our common stock, par value $0.0001, and a pre-funded warrant to purchase shares of common stock, the March Private Placement. The closing of the March Private Placement occurred on March 13, 2026. At the Closing, we issued and sold 1,179,508 shares at a purchase price of $1.854 per share and a pre-funded warrant to purchase up to 17,698,593 shares at a purchase price of $1.8539 per warrant share, the March Warrant Price, to the March Investor for gross proceeds to us of approximately $35.0 million.

We expect to use the net proceeds from the Private Placement and March Private Placement to accelerate the clinical development of EQ504 into a Phase 1 proof-of-mechanism study in mid-2026, with data expected to follow approximately six months thereafter. However, we cannot provide any assurances that we will be able to obtain data within those time frames or that the data which may be obtained will be favorable to the further clinical development of EQ504. With respect to the Private Placement, we cannot provide any assurances that the milestones related to the clinical study initiation and stock price conditions will be met or that the second closing will occur.

As of December 31, 2025, we had $30.3 million in cash and cash equivalents, which excludes $35.0 million of gross proceeds from the March Private Placement. We expect that our cash and cash equivalents as of the filing of this Annual Report on Form 10-K will enable us to fund our operations into 2029, based on certain assumptions and estimates that may prove to be inaccurate.

We have and will continue to pursue sources of additional capital, including pursuant to the Open Market Sales Agreement[SM], dated October 8, 2023, as amended August 3, 2025, with LifeSci Capital LLC, the 2023 ATM Facility, as well as other financing sources that may be available to us.

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 planned or future clinical studies of our product candidates may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expect.

We do not have sufficient funds to complete the clinical development of EQ504 or any of our product candidates. We will need to raise substantial additional capital to complete the development and commercialization of EQ504 and any other product candidates, which additional capital, if capable of being raised, may be raised through the sale of our common stock

or other securities or through the entering into of alternative strategic transactions, the terms of which may require us to divest one or more of our product candidates, or cause our stockholders to incur substantial dilution.

Future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of our planned or future nonclinical and clinical studies of EQ504, EQ302 and other future product candidates, including as such activities may be adversely impacted by public health epidemics or outbreaks, the evolving conflict between Russia and Ukraine, the conflict in the Middle East, bank failures, tariffs and inflationary pressures on the economy;
- the advancement and cost of preclinical research of EQ504, EQ302 and other novel preclinical drug candidates;
- the number and scope of indications we decide to pursue for the development of our product candidates;
- the cost, timing and outcome of regulatory review of any New Drug Application, or NDA, we may submit for our product candidates;
- the costs and timing of manufacturing EQ504 and other product candidates;
- the costs of drug formulation research and device development;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- our ability to enter into partnerships or otherwise monetize our pipeline through strategic transactions on a timely basis, on terms that are favorable to us, or at all;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies or engage in in-house discovery and preclinical research of new product candidates;
- the legal and other transactional costs associated with our business development activities;
- the cost associated with commercializing EQ504 or any of our other product candidates, if approved for commercial sale; and
- the cost, timing and impact of our new cryptocurrency treasury reserve strategy, if implemented.

In August 2025, we amended the 2023 ATM Facility with Jefferies LLC, to replace Jefferies LLC as the sales agent with LifeSci Capital LLC. Under the 2023 ATM Facility, we may offer and sell shares of our common stock having an aggregate offering price of up to $75.0 million from time to time through LifeSci Capital LLC acting as our sales agent. As of the filing of this Annual Report on Form 10-K, we have sold 1,719,485 shares under the 2023 ATM Facility.

Our commercial revenues, if any, are expected to be primarily derived from sales of products, which is unlikely to happen for at least several years, if ever. We will need to obtain substantial additional funding to continue our operations. Adequate additional financing may not be available to us on acceptable terms, or at all. Our ability to raise additional capital may be adversely impacted by the potential worsening global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from public health epidemics or outbreaks, potential tariffs, the conflict between Russia and Ukraine, the conflicts in the Middle East, government shutdowns and monetary policy changes of federal agencies that have increased interest rates to address inflationary pressures on the economy. If such disruptions persist and deepen, we could experience an inability to access additional capital. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations or enter into partnerships or otherwise monetize our pipeline through strategic transactions on terms that may not be as favorable to us as if we developed or commercialized the product candidates ourselves. Further, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions.

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

We are highly dependent on the successful planned or future development of our current product candidates, EQ504 and EQ302, and we may not be able to obtain regulatory or marketing approval of, or successfully commercialize, these product candidates in any of the indications for which we plan to develop them.

Our future success will depend almost entirely on our ability to successfully develop, obtain regulatory approval of and then successfully commercialize EQ504 or other product candidates, which may never occur. We currently generate no revenues from sales of any biopharmaceutical products, and we may never be able to develop or commercialize a marketable biopharmaceutical product.

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

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

We may enter into partnerships or similar arrangements or otherwise monetize our pipeline through strategic transactions for purposes of raising additional capital and allocating our available capital and other resources to developing and commercializing our other or future product candidates. For example, in October 2024, we entered into the Stock Purchase Agreement with all the stockholders of Ariagen to acquire control of that company and its preclinical stage therapeutic drug product, now referred to as EQ504. Despite our efforts, we may be unable to enter into future partnerships or otherwise monetize our pipeline through strategic transactions with third parties on favorable terms or at all. Supporting diligence activities conducted by third parties and negotiating the financial and other terms of a strategic arrangement are long, costly and complex processes with uncertain results, and we may fail to derive any financial benefit from these activities. Any efforts toward finding a strategic partner for one or more of our product candidates may divert the time and attention of our management away from their day-to-day activities, which may adversely affect our focus on the discovery and development of our current product candidates that we intend to continue to develop and commercialize. Further, potential strategic partners may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, potentially resulting in us receiving no future milestone or royalty payments under any such arrangement. We may enter into a strategic transaction for one or more of our product candidates that prove to be more successful than the product candidates we decide to continue to develop and commercialize. As a result, our financial position and the return we realize on our research and development activities could be negatively affected. Any of the foregoing could have a material adverse effect on our competitive position, business prospects, financial condition and results of operations.

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

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with biotechnology or pharmaceutical companies for the development and potential commercialization of product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish other strategic partnerships or alternative arrangements for any product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and potential parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate on the development and commercialization of product candidates, we can expect to relinquish some

or all of the control over the future success of that product candidate to the partner. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors, many of which may be out of our control.

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

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

We previously conducted four Phase 1 studies, one Phase 2 study and one Phase 3 study of discontinued product candidates and indications. To date we have not successfully completed late-stage clinical studies or obtained regulatory approval for any product candidate. Prior to initiating a clinical study of EQ504, data from animal toxicology studies will be required as well as formulation development. Because of our limited interaction with the FDA, we may not learn of certain information or data that the FDA may request until future interactions. In part because of our limited infrastructure, experience conducting clinical studies as a company and regulatory interactions, we also cannot be certain that our planned or future clinical studies will be completed on time, if at all, that our planned or future clinical studies will be initiated on time, if at all, or that our planned development programs would be acceptable to the FDA.

Adverse safety and toxicology findings may emerge as we conduct our planned or future nonclinical research or clinical studies. In addition, success in early clinical studies does not mean that later clinical studies will be successful, because later-stage clinical studies may be conducted in broader patient populations and involve different study designs. Furthermore, our planned or future clinical studies will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by the FDA. Companies frequently suffer significant setbacks in advanced clinical studies, even after earlier clinical studies have shown promising results, and we cannot be certain that we will not face similar setbacks. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical studies have nonetheless failed to obtain marketing approval of their products. In addition, only a small percentage of product candidates under development result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

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

- completion of our planned or future nonclinical and clinical studies with favorable results, including activities that may be adversely impacted by public health epidemics or outbreaks;
- acceptance of INDs by the FDA for our planned or future clinical studies, as applicable;
- timely and successful enrollment in, and completion of, our planned or future clinical studies with favorable results;

- demonstrating safety, efficacy and acceptable risk-benefit profile of our product candidates to the satisfaction of the FDA;
- receipt of marketing approvals from the FDA;
- maintaining arrangements with our CMOs for clinical supply and, if and when approved, commercial supply of EQ504 and EQ302, if we resume development;
- establishing sales, marketing and distribution capabilities and launching commercial sale of our product candidates, if and when approved in one or more indications;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; and
- maintaining a continued acceptable safety profile of our products, if and when approved.

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

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

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

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

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

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

We are vulnerable to the increasing impact of climate change and other natural disasters. Volatile changes in weather conditions, including extreme heat or cold, could increase the risk of wildfires, floods, blizzards, hurricanes and other weather-related disasters. Such extreme weather events, or other natural disasters such as earthquakes, can cause power outages and network disruptions that may result in disruption to operations and may impact our ability to continue or complete our planned or future clinical studies, which will negatively impact our operations and delay our plans to

commercialize our product candidates. Such disasters could also result in loss or damage to office buildings, laboratories, employee and/or patient homes, employees and/or patients relocating to other parts of the country or being unwilling to travel to the clinical study site locations, and the inability to recruit key employees and/or enroll patients. This could result in adverse impacts to the available workforce and/or patient samples, damage to or destruction of materials and/or data, or the inability to conduct planned or future clinical studies and deliver new data.

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

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

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

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

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

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

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

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

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

Before we can initiate our planned or future clinical studies of our product candidates in any distinct indication in the United States, we must submit the results of nonclinical studies to the FDA along with other information, including information about their chemistry, manufacturing and controls and our proposed clinical study protocol, as part of an IND or similar regulatory filing.

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

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

- the FDA or other applicable regulatory authorities disagreeing as to the design or implementation of our planned or future clinical studies;
- obtaining FDA or other applicable regulatory authorizations to commence a study or reaching a consensus with the applicable FDA regulators on study design;
- any failure or delay in reaching an agreement with CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- obtaining approval from one or more Institutional Review Boards, or IRBs;
- additional nonclinical pharmacology and toxicology studies to support planned or future Phase 2 and 3 clinical studies;
- IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the study;
- changes to clinical study protocol;
- clinical sites deviating from study protocol or dropping out of a study;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in planned or future clinical studies;
- subjects failing to enroll or remain in our study at the rate we expect, or failing to return for post-treatment follow-up;

- subjects choosing an alternative treatment, or participating in competing planned or future clinical studies;
- lack of adequate funding to continue the clinical study;
- cost of preclinical research and testing being greater than anticipated or greater than our available financial resources;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in studies of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA (or its own regulatory authorities if such facility is located outside the United States) to temporarily or permanently shut down or cease export of such materials due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, changes in export restrictions and controls, or infections or cross-contamination during the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- impacts and risks associated with global health epidemics or outbreaks;
- third-party clinical investigators losing the licenses or permits necessary to perform our planned or future clinical studies, not performing our planned or future clinical studies on our anticipated schedule or consistent with the clinical study protocol, Good Clinical Practices, or GCP, or other regulatory requirements;
- data collection or analysis in an untimely or inaccurate manner or improper disclosure of data prematurely or otherwise in violation of a clinical study protocol by us or our contractors; or
- our contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

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

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

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

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

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

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

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

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates in our planned or future clinical studies as well as in clinical studies, investigator-initiated studies and potential commercial usage.

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

It is possible that as we test our product candidates in larger, longer and more extensive planned or future clinical studies, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier studies, as well as

conditions that did not occur or went undetected in previous studies, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

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

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

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

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

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

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

We have previously and may in the future use sites outside of the United States for any future clinical studies, including for EQ504 and possibly EQ302 or any other future product candidates. The FDA may not accept data from any such studies, in which case our development plans will be delayed, which could materially harm our business.

We expect to be ready to initiate a first-in-human Phase 1 clinical study of EQ504 in mid-2026, and we may conduct this study at clinical sites outside of the United States. In addition, if we advance EQ302 or our other future product candidates into clinical studies, we may decide to utilize clinical sites in countries outside of the United States. Although the FDA may accept data from clinical studies conducted entirely outside of the United States and not under an IND, acceptance of such clinical study data is generally subject to certain conditions. For example, the FDA requires the clinical study to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical studies through an onsite inspection if it deems such inspection necessary. In addition, when clinical studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical study was inadequate, which would likely require us to conduct additional clinical studies. Conducting clinical studies outside the United States also exposes us to additional risks, including risks associated with:

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

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

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

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

Even if we receive regulatory approval of any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals of our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical studies, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves any product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for the product will be subject to extensive and ongoing regulatory requirements, which can be costly and time consuming. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with

cGMPs and GCPs, for any clinical studies that we conduct post-approval. We must incur significant expenses and spend time and effort to ensure compliance with these complex regulations. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, undesirable side effects caused by the product, problems encountered by our contracted manufacturers or manufacturing processes, or failure to comply with regulatory requirements, either before or after product approval, may result in, among other things:

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

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

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

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

If any of our product candidates receive marketing approval in any one or more indication, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become

profitable. The degree of market acceptance, if approved for commercial sale in any indication, will depend on a number of factors, including:

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

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

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

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

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

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

We are aware that other products addressing the same indications as EQ504 and EQ302 are in development, and some have been approved. There are multiple private and public companies with numerous active clinical development programs for the treatment of UC. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical studies, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we have. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, these larger companies may be able to use their greater market power to obtain more favorable distribution and sales-related agreements with third parties, which could give them a competitive advantage over us.

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

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and subject enrollment for clinical studies, as well as acquiring technologies complementary to, or necessary for, EQ504 and EQ302 or any future programs.

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

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

We have global rights to EQ504 and are initially planning to develop it as a potential treatment for UC and other GI diseases with potential indication expansion opportunities for the treatment of inflammatory lung diseases. We have global rights to EQ302, and although we have paused development activities of EQ302, we believe it may be a promising candidate for future development as a potential treatment of GI indications such as celiac disease. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates and may prove to be incorrect. Further, other stakeholders, including investors, analysts, and strategic partners may view the revenue potential of our product candidates as smaller than we do, which could impede our ability to enter into favorable business or financing transactions. If any of our estimates are inaccurate, the market opportunities for our product candidates could be significantly diminished and have an adverse material impact on our business.

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

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

rebates required by government healthcare programs or private payors, by any future laws limiting pharmaceutical prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

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

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

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

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

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

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

Risks Related to Manufacturing and Our Reliance on Third Parties

The manufacture of pharmaceutical products is complex and we may encounter difficulties in production, distribution and delivery of our product candidates. If CMOs encounter such difficulties, our ability to provide supply of our product candidates for our planned or future clinical studies, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, if approved, could be delayed or stopped.

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

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

Scaling up pharmaceutical manufacturing processes is a difficult and uncertain task, and our CMOs may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely deliver our supplies of EQ504 and EQ302 or other future product candidates or meet product demand.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, many of our suppliers are located outside of the United States, and our principal suppliers of critical raw materials and active pharmaceutical ingredients, or APIs, are

located in Europe and China, consistent with broader industry practices. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts. Contract manufacturing organizations may become subject to legislation, trade restrictions, sanctions, tariffs and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities or otherwise substantially increase our manufacturing costs, thereby potentially disrupting the supply of material to us or requiring us to scale back our manufacturing activities. For example, the United States has recently passed legislation, namely the BIOSECURE Act, to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a "biotechnology company of concern" or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology equipment or equipment. Specifically, on December 18, 2025, the President signed the National Defense Authorization Act, or NDAA, for fiscal year 2026 into law, which includes the BIOSECURE Act. The BIOSECURE Act prohibits the U.S. government from procuring or obtaining biotechnology equipment or services produced or provided by a "biotechnology company of concern," or BCC; entering into, extending, or renewing government contracts with an entity that directly or indirectly uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The BIOSECURE Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. Companies designated as a BCC include those that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. Government also has the ability to designate entities as BCCs through a separate designation process. Given the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology companies to the extent we would contract with, or otherwise receive funding from, the U.S. government.

Current or future tariffs would result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs would increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

We rely, and intend to continue to rely, on CROs to conduct our planned or future clinical studies and perform some of our planned or future research and nonclinical 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 planned or future nonclinical testing or clinical studies ourselves. As a result, we are and will be dependent on third parties to conduct our planned or future nonclinical and clinical studies of EQ504, EQ302 and any planned or future nonclinical and clinical studies of any other product candidates. The timing of the initiation and completion of these studies will therefore be partially controlled by such third parties and may result in delays to our development programs.

Specifically, we expect CROs, clinical investigators and consultants to play a significant role in the conduct of these studies and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities, and the effectiveness and capabilities of many of these CROs, clinical investigators and consultants will be unknown to us as we move the focus of our development activities to EQ504 and potentially EQ302. Nevertheless, we are responsible for ensuring that each clinical study is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. Should our CROs engage in unethical, illegal, or non-compliant activities, such behavior could adversely impact our business. Further, should we terminate our contractual relationship with a CRO for such improprieties, transitioning to a different CRO may delay, disrupt or otherwise adversely impact the progress of the clinical study. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of study sponsors, clinical study investigators and clinical study sites. If we or any of our CROs or clinical study sites fail to comply with applicable GCP requirements, the data generated in our planned or future clinical studies may be deemed unreliable, and the FDA may require us to perform additional clinical studies before approving our marketing applications. In addition, our planned or

future clinical studies must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical studies, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical study investigators or other third parties on which we rely on will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical study site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical study unless we are able to transfer those subjects to another qualified clinical study site, which may be difficult or impossible. In addition, clinical study investigators for our clinical study may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA. Any such delay or rejection could prevent us from commercializing EQ504, EQ302 or any future products.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical studies or other biopharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our planned or future clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals of EQ504 and EQ302 or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

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

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

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

Risks Related to Intellectual Property

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

Our success depends in significant part on our ability to establish, maintain and protect patents and other intellectual property rights with respect to our proprietary technologies, research programs, and product candidates including EQ504 and EQ302, and operate without infringing the intellectual property rights of others. The patent prosecution process is expensive and time-consuming, and we and any 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 any 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. If any 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 any future licensors, licensees or partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, allowing foreign competitors a better opportunity to create, develop and market competing product candidates, or vice versa. We cannot be certain that the claims in our pending patent applications directed to our product candidates such as EQ504 and EQ302 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 any future licensors', licensees' or partners' patent rights are highly uncertain. Our and any future 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 any future licensors, licensees or partners, to narrow the scope of the claims of our or any future 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 have filed have not resulted in issued patents because we 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 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 were the first to file any patent application related to our research programs and product candidates such as EQ504 and EQ302. 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 EQ504 and EQ302 or any other product candidates that we may identify, our business may be materially harmed.

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

In the future, we may need to obtain 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 EQ504, EQ302 and/or others. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

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

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

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

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

We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to our therapeutic research programs or necessary for the commercialization of our product candidates such as EQ504, EQ302 and/or others in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties, and there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products and/or product candidates that we may identify. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products if and when approved. 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 EQ504, EQ302 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 if and when approved.

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 EQ504, EQ302 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 EQ504, EQ302 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 planned or future product candidates, including EQ504, EQ302, and others, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, we 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 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 planned or future clinical studies, continue our planned or future research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring EQ504, EQ302 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, if we resume development activities, including EQ504 or EQ302, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

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

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. 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 planned or future product candidates such as EQ504, EQ302, and others as well as their respective methods of use, manufacture and formulations thereof, our competitive position would be adversely affected, as, for example, competitors might be able to enter the market earlier than would otherwise have been the case.

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

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

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

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

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

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

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

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

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

We currently have two U.S. trademark registrations for EQUILLIUM respectively covering Classes 5 and 42, and one Canadian trademark registration for EQUILLIUM covering both Classes 5 and 42. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or potential 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 any future licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

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

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

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

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

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

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

personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical study data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to penalties, including criminal penalties, if we knowingly obtain, use, or disclose

individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and operations. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, collectively the CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA imposes fines for intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical studies, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, may also exempt some data processed in the context of clinical studies, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

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

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

In particular, several jurisdictions around the globe, including Europe and certain U.S. states, have proposed, enacted, or are considering laws governing AI/ML, including the EU's Artificial Intelligence Act. We expect other jurisdictions will adopt similar laws. Regulatory or contractual obligations related to AI/ML may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

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

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

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

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

Additionally, on April 8, 2025, the U.S. Department of Justice implemented a final rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons (the "Rule"), which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, employment of certain individuals, and investor agreements. If there is no lawful manner under the Final Rule for us to transfer sensitive personal data or if the requirements for a legally-compliant transfer under the Final Rule are too onerous, we could face significant adverse consequences, including the degradation of our operations or the need to relocate part or all of our business, personnel and/or data processing activities to other jurisdictions (such as the United States). Our failure to implement or have in place controls for identifying covered transactions, conduct appropriate diligence on our business partners, or implement compliance strategies could result in violations of the Rule. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

Also, in Europe, the Network and Information Security Directive ("NIS2") regulates resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Non-compliance with NIS2 may lead up to administrative fines of a maximum of 10 million Euros or up to 2% of the total worldwide revenue of the preceding fiscal year.

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

We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

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

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and

imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

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

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

As of December 31, 2025, we had aggregate U.S. federal net operating loss, or NOL, carryforwards of approximately $139.8 million that were generated after December 31, 2017. Under current U.S. federal income tax law, U.S. federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such U.S. federal NOLs is generally limited to 80% of taxable income. Certain states apply similar provisions.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage-point cumulative change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We completed an ownership change analysis through December 31, 2024 and determined that our ability to offset taxable income in 2024 is not expected to be impacted by ownership changes occurring prior to that date. Due to our estimated U.S. tax loss for the year ended December 31, 2025, we do not expect to utilize tax attribute carryforwards in 2025. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which may be outside of our control. As a result, our ability to use our pre-ownership change NOL carryforwards to offset U.S. federal taxable income in the future (if we earned net taxable income) and any other pre-ownership change tax attributes may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, on June 27, 2024, California Senate Bill 167 was enacted, which imposes limits for certain taxpayers on the usability of California state NOLs and certain California state tax credits in tax years beginning on or after January 1, 2024, and before January 1, 2027.

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 clinical studies. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop or commercialize our product candidates in Australia and New Zealand, including conducting clinical studies. Furthermore, we have no assurance that the results of any clinical studies that we conduct for our product candidates in Australia and New Zealand will be accepted by the FDA or other foreign regulatory authorities for development and commercialization approvals.

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

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

There have been, and continue to be, numerous legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we are able to 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 ACA substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There have been judicial, Congressional and executive challenges to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. On July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. 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 when and if approved and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the IRA, among other things, (1) directs HHS to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least seven years and biologics that have been on the market for at least eleven years covered under Medicare, or the Medicare Drug Price Negotiation Program, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, which take effect in January 2026. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The IRA's drug pricing reforms have the potential to adversely impact our ability to successfully commercialize our product candidates and could lessen the real or perceived value of our product candidates, which would negatively impact our business.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the

Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, (TrumpRx) U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again, or MAHA, Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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

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

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

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

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any future product candidates for which we obtain marketing approval. Our arrangements with third-party payors and potential 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 yet have any products approved for marketing and sale, 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 ACA 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 ACA 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 ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and their subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties,

amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the U.S. federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- 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 ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians, as defined by such law, other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; track and report gifts, compensation and other remuneration provided to physicians, other health care providers, and certain health care entities; report information related to drug pricing; and/or ensure the registration and compliance of sales personnel. Additionally, some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction. Further, 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 our product candidates such as EQ504 and EQ302 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 EQ504 and EQ302 or any future product candidates, if approved, to be in violation of applicable laws.

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

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

compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

Risks Related to Ownership of our Common Stock

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

The market price of our common stock has fluctuated in the past and may fluctuate significantly in the future in response to numerous factors, many of which are beyond our control, including:

- our operating performance and the performance of other similar companies;
- our ability to enroll and retain subjects in our planned or future clinical studies if we are able to raise additional capital to continue the development of our product candidates;
- results from our planned or future clinical studies with our current and future product candidates, and the results of the clinical studies of our competitors;
- the timing of data from our planned or future clinical studies of EQ504 and EQ302 and potentially other product candidates;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments of ours, our competitors';
- 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 candidate development goals in the timeframe we announce;
- announcements of clinical study results, regulatory developments, acquisitions or mergers, strategic alliances or significant agreements by us, by our competitors;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a substantial proportion of our outstanding common stock;
- the registration and subsequent sale of the Shares and Warrant Shares issued in the Private Placement;

- the size of our market float;
- the impact of a reverse stock split, if any;
- delays or other adverse impacts to our planned or future clinical studies from global health epidemics or outbreaks;
- taxation authorities, such as the IRS and ATO, disagreeing with the positions taken on our tax returns; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations, including as a result of global pandemics, bank failures, tariffs, the conflict between Russia and Ukraine, and the conflict in the Middle East, that have affected and may continue to affect the market prices of equity securities of many life sciences companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

We have in the past and may in the future fail to maintain compliance with the listing requirements of the Nasdaq Capital Market, and as a result, our common stock may be delisted from the Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it difficult for you to sell your shares.

Our common stock is listed on the Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from the Nasdaq Capital Market.

On December 13, 2024, we received a notice, or Notice, from the Nasdaq Stock Market, or Nasdaq, that we were not then in compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Price Requirement. The Notice indicated that, consistent with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 days, or until June 11, 2025, to regain compliance with the Minimum Bid Price Requirement by having the bid price of our common stock meet or exceed $1.00 per share for at least ten consecutive business days. The Notice had no immediate effect on the listing of our common stock, and our common stock continued to trade on the Nasdaq Capital Market under the symbol "EQ". On June 12, 2025, we received a notice from Nasdaq that we had been granted an additional 180 days, or until December 8, 2025, to regain compliance with the Minimum Bid Price Requirement. On August 29, 2025, we received a letter from Nasdaq notifying us that the closing bid price of our common stock had met or exceeded $1.00 per share for at least ten consecutive business days, from August 15, 2025 through August 28, 2025, and accordingly, we had regained compliance with Nasdaq Listing Rule 5550(a)(2).

There can be no assurance, however, that we will maintain compliance with the continued listing requirements for the Nasdaq Capital Market or that our common stock will not be delisted in the future. In addition, we may be unable to meet other applicable listing requirements of the Nasdaq Capital Market, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be subject to delisting.

Delisting from the Nasdaq Capital Market would adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

If we are delisted from Nasdaq and we are not able to list our common stock on another exchange, our common stock could be quoted on the OTC Bulletin Board or in the "pink sheets." As a result, we could face significant adverse consequences including, among others:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and little or no analyst coverage for us;

- an inability to qualify for exemptions from state securities registration requirements, which may require us to comply with applicable state securities laws; and
- a decreased ability to issue additional securities (including pursuant to registration statements on Form S-3) or obtain additional financing in the future.

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

On March 13, 2026, we issued and sold 1,179,508 shares at a purchase price of $1.854 per share and a pre-funded warrant to purchase up to 17,698,593 shares at a purchase price of $1.8539 per warrant share, to the investor for gross proceeds to us of approximately $35.0 million in connection with the March Private Placement.

On August 12, 2025, we issued and sold 21,814,874 shares at a purchase price of $0.57 per share and pre-funded warrants to purchase up to 30,816,705 shares at a purchase price of $0.5699 per warrant share, to the investors for gross proceeds to us of approximately $30.0 million in connection with the Private Placement. Additionally, the Purchase Agreement provides for a potential second closing for up to approximately $20.0 million in gross proceeds in exchange for up to approximately 35,087,717 shares of common stock, subject to achieving certain specified milestones related to clinical study initiation and stock price conditions or waiver thereof.

In October 2023, we entered into the 2023 ATM Facility with Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $21.95 million from time to time through Jefferies acting as our sales agent. On August 3, 2025, we entered into Amendment No. 1 to the 2023 ATM Facility pursuant to which Jefferies LLC was replaced by LifeSci Capital LLC as the sales agent under the 2023 ATM Facility. On September 19, 2025, we filed a prospectus supplemental with the SEC under which we may offer and sell shares of our common stock having an aggregate offering price of up to $75.0 million, pursuant to the 2023 ATM Facility, as amended. For the year ended December 31, 2025, we sold 1,719,485 shares under the 2023 ATM Facility, as amended, for gross proceeds of approximately $1.0 million. As of December 31, 2025 and through the date of the filing of this Annual Report on Form 10-K, we have not sold any additional shares under the 2023 ATM Facility, as amended.

As of March 20, 2026, we had 63,226,556 shares of common stock outstanding, which excludes the pre-funded warrant shares totaling 30,816,705 related to the Private Placement and 17,698,593 related to the March Private Placement until they are exercised. The sale of our shares of common stock and pre-funded warrants has significantly diluted the ownership interest of our stockholders from their ownership interest before such sales, and the potential sale of additional shares of common stock and pre-funded warrants if the second closing occurs will continue to significantly dilute their ownership interest. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will continue to be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

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

If we raise funds through collaboration and license agreements with third parties, 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. In connection with the Private Placement and March Private Placement, we agreed, pursuant to the applicable Registration Rights Agreement, to register for resale the shares of common stock issued, and warrant shares issuable upon exercise of the pre-funded warrants, to the investors. The number of shares of common stock to be registered by us is significant. At such time as these shares of common stock become registered in an

effective registration statement, they may be sold by the investors into the market and may cause the price of our common stock to decline, and the market perception that such sales may occur may also cause the price of our common stock to decline. We have also 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. Even though shares held by directors, executive officers and other affiliates are subject to volume limitations under Rule 144 under the Securities Act, the sale of shares by directors, executive officers and other affiliates may cause the price of our common stock to decline.

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 have indemnity obligations and other responsibilities under the registration rights agreement and securities purchase agreement entered into with investors on August 12, 2025 and March 13, 2026. If these obligations are not met, we may be required to pay damages and indemnify the investors.

The registration rights agreement obligates us to file registration statements in a timely manner to register shares sold to investors and maintain their effectiveness to enable the sale of shares by the investors. If we fail to meet these requirements, or if investors cannot sell their shares, we may have to pay damages to the investors of up to 5% of the total purchase price for the shares under the securities purchase agreement.

We are required to indemnify investors for breaches of our representations, warranties or covenants in the securities purchase agreement. The registration rights agreement also has indemnity obligations for inaccuracies or omissions in registration statements or prospectuses, or violations of securities laws. If we are required to indemnify the investors the costs could be material.

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); 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 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 General Corporation Law of the State of Delaware, or DGCL. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

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

Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects.

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

Risks Related to Our Crypto Treasury Strategy

Cryptocurrencies are highly volatile assets, and fluctuations in the price of cryptocurrencies are likely to influence our financial results and the market price of our common stock.

In August 2025 we announced the expansion of our treasury strategy to include digital currencies for the diversification, liquidity and long-term capital appreciation potential they represent, and we updated our treasury investment policy to permit such investments. We have not initiated our cryptocurrency treasury strategy but we may in the future invest in or otherwise acquire digital currencies.

Cryptocurrencies are highly volatile assets, and significant fluctuations in the price of cryptocurrencies over short periods of time are likely to influence our financial results and the market price of our common stock. Our financial results and the market price of our common stock would be adversely affected, and our business and financial condition would be negatively impacted, if the price of cryptocurrency decreased substantially (as it has in the past, such as during 2022), including as a result of:

- decreased user and investor confidence in cryptocurrency, including due to the various factors described herein;
- investment and trading activities such as (i) trading activities of highly active retail and institutional users, speculators, miners and investors, or of the U.S. or state governments, (ii) actual or expected significant dispositions of cryptocurrency by large holders, and (iii) actual or perceived manipulation of the spot or derivative markets for cryptocurrency or spot cryptocurrency exchange-traded products, or ETPs;
- negative publicity, media or social media coverage, or sentiment due to events in or relating to, or perception of, cryptocurrency or the broader digital assets industry, for example, (i) public perception that cryptocurrency can be used as a vehicle to circumvent sanctions, including sanctions imposed on Russia or certain regions related to the ongoing conflict between Russia and Ukraine, or to fund criminal or terrorist activities, such as the purported use of digital assets by Hamas to fund its terrorist attack against Israel in October 2023; (ii) expected or pending civil, criminal, regulatory enforcement or other high profile actions against major participants in the cryptocurrency ecosystem, including potential future SEC enforcement actions; (iii) additional filings for bankruptcy protection or bankruptcy proceedings of major digital asset industry participants, such as the bankruptcy proceeding of FTX Trading and its affiliates; and (iv) the actual or perceived environmental impact of cryptocurrency and related activities, including environmental concerns raised by private individuals, governmental and non-governmental organizations, and other actors related to the energy resources consumed in the cryptocurrency mining process;
- changes in consumer preferences and the perceived value or prospects of cryptocurrency;
- competition from other digital assets that exhibit better transaction speed, security, scalability, or energy efficiency, that feature other more favored characteristics, that are backed or held in large amounts by governments, including the U.S. government, or reserves of fiat currencies, or that represent ownership or security interests in physical assets;
- a decrease in the price of other digital assets, including stablecoins, or the crash or unavailability of stablecoins that are used as a medium of exchange for cryptocurrency purchase and sale transactions, such as the crash of the stablecoin Terra USD in 2022, to the extent the decrease in the price of such other digital assets or the unavailability of such stablecoins may cause a decrease in the price of cryptocurrency or adversely affect investor confidence in digital assets generally;
- disruptions, failures, unavailability, or interruptions in service of trading venues for cryptocurrency, such as, for example, the announcement by the digital asset exchange FTX Trading that it would freeze withdrawals and transfers from its accounts and subsequent filing for bankruptcy protection or an SEC enforcement action

brought against an exchange or other trading venue, which seeks to freeze all of its assets during the pendency of the enforcement action;

- the filing for bankruptcy protection by, liquidation of, or market concerns about the financial viability of digital asset custodians, trading venues, lending platforms, investment funds, or other digital asset industry participants, such as the filing for bankruptcy protection by digital asset trading venues FTX Trading and BlockFi and digital asset lending platforms Celsius Network and Voyager Digital Holdings in 2022, the ordered liquidation of the digital asset investment fund Three Arrows Capital in 2022, the announced liquidation of Silvergate Bank in 2023, the government-mandated closure and sale of Signature Bank in 2023, the placement of Prime Trust, LLC into receivership following a cease-and-desist order issued by the Nevada Department of Business and Industry in 2023, and the exit of Binance Holdings Ltd. from the U.S. market as part of its settlement with the Department of Justice and other federal regulatory agencies;
- regulatory, legislative, enforcement and judicial actions that adversely affect the price, ownership, transferability, trading volumes, legality or public perception of cryptocurrency, or that adversely affect the operations of or otherwise prevent digital asset custodians, trading venues, lending platforms or other digital assets industry participants from operating in a manner that allows them to continue to deliver services to the digital assets industry;
- transaction congestion and fees associated with processing transactions on the applicable cryptocurrency network;
- macroeconomic changes, such as changes in the level of interest rates and inflation, fiscal and monetary policies of governments, trade restrictions, and fiat currency devaluations;
- developments in mathematics or technology, including in digital computing, algebraic geometry and quantum computing, that could result in the cryptography used by the cryptocurrency blockchain becoming insecure or ineffective; and
- changes in national and international economic and political conditions, including, without limitation, the adverse impact attributable to the economic and political instability caused by the current conflict between Russia and Ukraine and the economic sanctions adopted in response to the conflict, and the ongoing conflicts in the Middle East, as well as expectations regarding changes to the regulatory environment, including for the U.S. digital asset industry.

We may use the net proceeds from any offering by the company to purchase cryptocurrencies, the price of which has been, and will likely continue to be, highly volatile.

Except for the proceeds from the Private Placement and the March Private Placement, we may use the net proceeds from any offering by the company, including the Open Market Sale Agreement[SM], dated October 5, 2023, as amended August 3, 2025, or the Agreement, between LifeSci Capital LLC and us, to purchase cryptocurrencies. Cryptocurrencies are highly volatile and do not pay interest or other returns, and, as a result, our ability to generate a return on any investments into cryptocurrencies from the net proceeds from any offering will depend on whether there is appreciation in the value of the cryptocurrencies we purchase, if any, following our purchases thereof with the net proceeds from such offering. Future fluctuations in cryptocurrency trading prices may result in our converting cryptocurrencies purchased with the net proceeds from an offering, if any, into cash with a value substantially below the net proceeds from such offering.

Cryptocurrency and other digital assets are novel assets, and are subject to significant legal, commercial, regulatory and technical uncertainty.

Cryptocurrency and other digital assets are relatively novel and are subject to significant uncertainty, which could adversely impact their price. The application of state and federal securities laws and other laws and regulations to digital assets is unclear in certain respects and evolving, and it is possible that regulators in the United States or foreign countries may interpret or apply existing laws and regulations in a manner that adversely affects the price of digital assets or results in increased compliance costs, limitations on our business model, or the forced liquidation of our digital asset holdings, if any. We may also be subject to enforcement actions or penalties if our activities are deemed to violate applicable laws or regulations.

The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of cryptocurrency or the ability of individuals or institutions such as us to own or transfer cryptocurrency. For example, in July 2025 the United States

enacted the Guiding and Establishing National Innovation for U.S. Stablecoins Ac, or the GENIUS Act, the first federal statute establishing prudential requirements for the issuance, reserve backing and supervision of U.S.-dollar-pegged stablecoins. In the same week, the House of Representatives passed the Digital Asset Market CLARITY Act of 2025, or the CLARITY Act, which—if ultimately enacted—would allocate jurisdiction between the SEC and Commodity Futures Trading Commission and create a market-structure framework for digital commodities; the bill now awaits Senate action. International laws, including the European Union's Markets in Crypto Assets Regulation and the U.K.'s Financial Services and Markets Act 2023 have also recently taken effect.

It is also not possible to predict the nature of any such additional authorities, how additional legislation or regulatory oversight—such as the implementing regulations under the GENIUS Act or any Senate amendments to the CLARITY Act—might impact the ability of digital asset markets to function or the willingness of financial and other institutions to continue to provide services to the digital assets industry, nor how any new regulations or changes to existing regulations might impact the value of digital assets generally and cryptocurrency specifically. The consequences of increased or different regulation of digital assets and digital asset activities could adversely affect the market price of cryptocurrency and in turn adversely affect the market price of our common stock.

Moreover, the risks of engaging in a cryptocurrency treasury strategy are relatively novel and have created, and could continue to create, complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

The growth of the digital assets industry in general, and the use and acceptance of cryptocurrency in particular, may also impact the price of cryptocurrency and is subject to a high degree of uncertainty. The pace of worldwide growth in the adoption and use of cryptocurrency may depend, for instance, on public familiarity with digital assets, ease of buying, accessing or gaining exposure to cryptocurrency, institutional demand for cryptocurrency as an investment asset, the participation of traditional financial institutions in the digital assets industry, consumer demand for cryptocurrency as a means of payment, and the availability and popularity of alternatives to cryptocurrency. Even if growth in cryptocurrency adoption occurs in the near or medium-term, there is no assurance that cryptocurrency usage will continue to grow over the long-term.

Recent actions by U.S. banking regulators have reduced the ability of cryptocurrency-related services providers to gain access to banking services and liquidity of digital assets may also be impacted to the extent that changes in applicable laws and regulatory requirements negatively impact the ability of exchanges and trading venues to provide services for cryptocurrency and other digital assets.

In addition, while the current administration has expressed support regarding the development and use of digital assets and the US recently enacted the GENIUS Act, the specific regulatory frameworks, including the potential adoption of the CLARITY Act, are still to be developed. Expectations around U.S. digital asset policy, including potential sentiments that the U.S. government is not moving quickly enough or not meeting policy expectations, may adversely affect the price of cryptocurrency.

Cryptocurrency holdings are less liquid than our existing cash and cash equivalents and may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents.

Historically, the cryptocurrency markets have been characterized by significant volatility in price over short periods of time, limited liquidity and trading volumes compared to sovereign currencies markets, relative anonymity, a developing regulatory landscape, potential susceptibility to market abuse and manipulation, compliance and internal control failures at exchanges, and various other risks inherent in its entirely electronic, virtual form and decentralized network. During times of market instability, we may not be able to sell our digital assets at favorable prices or at all. For example, a number of cryptocurrency trading venues temporarily halted deposits and withdrawals in 2022. As a result, cryptocurrency holdings may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents. Further, cryptocurrency we will hold with our custodians and transact with our trade execution partners does not enjoy the same protections as are available to cash or securities deposited with or transacted by institutions subject to regulation by the Federal Deposit Insurance Corporation or the Securities Investor Protection Corporation. Additionally, we may be unable to enter into term loans or other capital raising transactions collateralized by our unencumbered cryptocurrencies or otherwise generate funds using cryptocurrency holdings, including in particular, during times of market instability or when the price of cryptocurrencies has declined significantly. If we are unable to sell digital assets, enter into additional capital raising transactions using cryptocurrency as collateral, or otherwise generate funds using cryptocurrency holdings, or if we are forced to sell cryptocurrency at a

significant loss, in order to meet our working capital requirements, our business and financial condition could be negatively impacted.

We may face risks relating to the custody of our cryptocurrency, if any, including the loss or destruction of private keys required to access our cryptocurrency and cyberattacks or other data loss relating to our cryptocurrency.

If purchased, we would hold our cryptocurrency with regulated custodians that will have duties to safeguard our private keys. Custodial services contracts may restrict our ability to reallocate our cryptocurrency among custodians, and our cryptocurrency holdings may be concentrated with a single custodian from time to time. In light of the significant amount of cryptocurrency we intend to hold, we expect to continually seek to engage additional regulated custodians to achieve a greater degree of diversification in the custody of our cryptocurrency (if any) as the extent of potential risk of loss is dependent, in part, on the degree of diversification. If there is a decrease in the availability of regulated digital asset custodians that we believe can safely custody our cryptocurrency (if any), for example, due to regulatory developments or enforcement actions that cause custodians to discontinue or limit their services in the United States, we may need to enter into agreements that are less favorable than those currently being offered or take other measures to custody our cryptocurrency (if any), and our ability to seek a greater degree of diversification in the use of custodial services would be materially adversely affected. In addition, holding cryptocurrency with regulated custodians could affect the availability of receiving digital assets that may result from "forks" of various cryptocurrency blockchains if custodians are unable to support or otherwise provide us with such digital assets, thereby reducing the amount of digital assets we may hold as a result. While custodians may carry insurance policies designed to cover losses for commercial crimes, cyber and cold storage, the policy limits vary per provider and would be shared among all of their customers, and subject to various limitations and exclusions (such as if a loss arises due to our failure to protect login credentials and devices), and we cannot be sure that such coverage will continue to be available on terms that are commercially reasonable to our future custodians or at all. The insurance that covers losses of cryptocurrency holdings may cover only a small fraction of the value of the entirety of cryptocurrency holdings, and there can be no guarantee that such insurance will be maintained as part of the custodial services we may have or that such coverage will cover losses with respect to our cryptocurrency (if any). Moreover, our intended use of custodians exposes us to the risk that the cryptocurrency our future custodians may hold on our behalf could be subject to insolvency proceedings and we could be treated as a general unsecured creditor of the custodian, inhibiting our ability to exercise ownership rights with respect to such cryptocurrency. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our cryptocurrency.

Cryptocurrency is controllable only by the possessor of both the unique public key and private key(s) relating to the local or online digital wallet in which the cryptocurrency is held. While cryptocurrency blockchain ledgers require a public key relating to a digital wallet to be published when used in a transaction, private keys must be safeguarded and kept private in order to prevent a third party from accessing the cryptocurrency held in such wallet. To the extent the private key(s) for a digital wallet are lost, destroyed, or otherwise compromised and no backup of the private key(s) is accessible, neither we nor our custodians will be able to access the cryptocurrency held in the related digital wallet. Furthermore, we cannot provide assurance that our digital wallets, nor the digital wallets of our custodians held on our behalf, will not be compromised as a result of a cyberattack or other source of compromise. The cryptocurrency and blockchain ledger, as well as other digital assets and blockchain technologies, have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities.

Regulatory change reclassifying cryptocurrency as a security could lead to our classification as an "investment company" under the Investment Company Act of 1940, or the 1940 Act, and could adversely affect the market price of cryptocurrencies and the market price of our common stock.

Under Sections 3(a)(1)(A) and (C) of the 1940 Act, a company generally will be deemed to be an "investment company" for purposes of the 1940 Act if (1) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (2) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. We do not believe that we are an "investment company," as such term is defined in the 1940 Act, and are not registered as an "investment company" under the 1940 Act as of the date of this Quarterly Report on Form 10-Q.

While senior SEC officials have stated their view that cryptocurrency is not a "security" for purposes of the federal securities laws, a contrary determination by the SEC could lead to our classification as an "investment company" under the 1940 Act, if the portion of our assets consisting of investments in cryptocurrencies exceeds the 40% safe harbor limits prescribed in the 1940 Act, which would subject us to significant additional regulatory controls that could have a material adverse effect on

our business and operations and may also require us to change the manner in which we conduct our business. We may also be subject to enforcement actions or penalties if our activities are deemed to violate applicable laws or regulations.

We monitor our assets and income for compliance under the 1940 Act and seek to conduct our business activities in a manner such that we do not fall within its definitions of "investment company" or that we qualify under one of the exemptions or exclusions provided by the 1940 Act and corresponding SEC regulations. If cryptocurrency is determined to constitute a security for purposes of the federal securities laws, we would take steps to reduce the percentage of digital assets that constitute investment assets under the 1940 Act. These steps may include, among others, selling digital assets that we might otherwise hold for the long term and deploying our cash in non-investment assets, and we may be forced to sell our digital assets, if any, at unattractive prices. We may also seek to acquire additional non-investment assets to maintain compliance with the 1940 Act, and we may need to incur debt, issue additional equity or enter into other financing arrangements that are not otherwise attractive to our business. Any of these actions could have a material adverse effect on our results of operations and financial condition. Moreover, we can make no assurance that we would successfully be able to take the necessary steps to avoid being deemed to be an investment company in accordance with the safe harbor. If we were unsuccessful, and if cryptocurrency is determined to constitute a security for purposes of the federal securities laws, then we would have to register as an investment company, and the additional regulatory restrictions imposed by 1940 Act could adversely affect the market price of cryptocurrency and in turn adversely affect the market price of our common stock.

We do not currently have the expertise to implement our cryptocurrency treasury reserve strategy and may fail to identify qualified individuals or asset managers to develop and execute successful investment or trading strategies.

We do not currently have the expertise to successfully implement our cryptocurrency treasury reserve strategy. For our cryptocurrency treasury reserve strategy to be successful it will require us to identify and hire or engage qualified individuals or asset managers to implement and oversee our investment strategy. For example, many companies that have implemented cryptocurrency treasury strategies enter into asset management agreements pursuant to which the asset manager has broad discretion to invest the company's capital in furtherance of their applicable cryptocurrency treasury strategy. We may not be able to identify such managers in a timely manner or be able to agree on favorable terms, if at all. If identified and hired or engaged, we will be dependent on such persons to identify overvalued and undervalued investment opportunities, to exploit price discrepancies and help us navigate the complex and evolving legal and regulatory framework that governs cryptocurrencies and digital assets more broadly. No assurance can be given that we or our advisors will be able to identify suitable or profitable investment opportunities in which to deploy our capital.

Future developments regarding the treatment of digital assets for U.S. federal income and applicable state, local and non-U.S. tax purposes could adversely impact our business.

Due to the new and evolving nature of digital assets and the absence of comprehensive legal guidance with respect to digital assets and related transactions, many significant aspects of the U.S. federal income and applicable state, local and non-U.S. tax treatment of transactions involving digital assets, are uncertain, and it is unclear what guidance may be issued in the future with respect to the tax treatment of acquiring digital assets and related transactions. Current IRS guidance does not address all significant aspects of the U.S. federal income tax treatment of digital assets and related transactions and there continues to be uncertainty with respect to the timing and amount of income inclusions for various digital asset transactions. There can be no assurances that the IRS will not issue future guidance with respect to digital assets or that a court will not interpret existing (or new) guidance in a manner that has negative tax consequences including the imposition of a greater tax burden on investors in digital assets or imposing a greater cost on the acquisition and disposition of digital assets.

General Risk Factors

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

Companies that file reports with the SEC, including us, are subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires management to establish and maintain a system of internal control over financial reporting, and annual reports on Form 10-K filed under the Exchange Act, must contain a report from management assessing the effectiveness of a company's internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis remains a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause our stock price to decline as a result.

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

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

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

Our headquarters and main research facility are located in the Greater San Diego Area, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events, including public health epidemics or outbreaks, that could impact our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our planned or future clinical studies, our development plans and business.

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

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

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

We face an inherent risk of product liability exposure related to the testing of EQ504 and EQ302 and any future product candidates which may go into human clinical studies and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that EQ504 and EQ302 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 planned or future clinical studies;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical study subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to clinical study subjects or patients;
- product recalls, withdrawals or labeling, or marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently have product liability insurance. However, the amount of insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as EQ504, EQ302 and any future product candidates advance through potential future clinical studies and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Changes in tax laws or regulations that are applied adversely to us or our potential 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. For example, the U.S. government recently enacted the OBBBA, that (along with other recent U.S. federal tax reform) has resulted in significant changes to the taxation of business entities including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. The Trump administration and the U.S. Congress could also enact other tax law changes that could have an adverse effect on our operations, cash flows and results from operations and contribute to overall market volatility. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation.

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

We are subject to income taxes in the United States and various state jurisdictions, as well as Australia. The preparation of these income tax returns requires us to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid. Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We periodically assess the likelihood and amount of potential revisions and, if warranted, adjust the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known. An amount is accrued for the estimate of additional tax liability, if any, including interest and penalties, for any uncertain tax positions taken or expected to be taken in an income tax return. Significant judgments based on interpretations of existing tax laws or regulations are required in determining the

provision for income taxes. Our provision for income taxes could be adversely affected by various factors, including, but not limited to, changes in the mix of earnings in tax jurisdictions with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in existing tax policies, laws, regulations, or rates, changes in the level of non-deductible expenses (including stock-based compensation), location of operations, changes in our future levels of research and development spending, mergers and acquisitions, or the result of examinations by various tax authorities. Although we believe our tax estimates are reasonable, if the Internal Revenue Service or other taxing authority disagrees with the positions taken on our tax returns, we could have additional tax liability, including interest and penalties. If material, payment of such additional amounts upon final adjudication of any disputes could have a material impact on our results of operations and financial position.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk management and strategy

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

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

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

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

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

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

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

Governance

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

Our cybersecurity risk assessment and management processes are implemented and maintained by certain company management, including our Head of IT and our Chief Operating Officer. Our Head of IT has over 30 years of IT experience in both public and private companies in the biotech pharmaceutical industry and is a Microsoft Certified Professional in Microsoft technologies. He has experience in evaluating and implementing tools and technologies that enable defense and response capabilities, developing critical cybersecurity procedures, training, and awareness programs. The Head of IT reports directly to our Chief Operating Officer who provides executive oversight of cybersecurity risk management and has over 30 years of experience with public companies in the biotech pharmaceutical industry overseeing operational and enterprise risk management processes, including the review of cybersecurity risks and mitigation strategies with management. In addition, our Chief Operating Officer has a Cybersecurity for Directors certificate from the Corporate Governance Institute.

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

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

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

Item 2. Properties.

We lease a total of approximately 5,545 square feet of office space for our current headquarters in La Jolla, California under leases that expire in February 2027. We also lease a total of approximately 5,086 square feet of laboratory space in San Diego, California, under a lease that expires in January 2028.

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

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

Holders of Record

As of March 20, 2026, there were approximately 39 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

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

Securities Authorized for Issuance Under Our Equity Compensation Plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

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

Overview

We are a biotechnology innovator developing novel therapies to treat severe autoimmune and inflammatory disorders with the mission to develop life-changing therapeutics for patients. Our primary goal is to advance EQ504, our novel aryl hydrocarbon receptor, or AhR, modulator, into and through clinical development.

As of December 31, 2025, we had $30.3 million in cash and cash equivalents, excluding the gross proceeds of approximately $35.0 million from the closing of the March Private Placement (defined below). From inception through December 31, 2025, substantially all of our efforts have been focused on research, development and the advancement of our clinical and preclinical product candidates. We have not yet generated product sales and as a result have incurred significant operating losses and negative cash flows from operations. As a result, we had an accumulated deficit of $216.2 million as of December 31, 2025. We expect to incur additional losses in the future to conduct research and development for which we will need to raise additional capital to implement.

On August 10, 2025, we entered into a Securities Purchase Agreement, the Purchase Agreement, with certain institutional and accredited investors, the Investors, pursuant to which we agreed to sell and issue shares of our common stock, par value $0.0001 per share, and pre-funded warrants to purchase shares of common stock, in up to two closings in a private placement transaction, the Private Placement. The initial closing of the Private Placement occurred on August 12, 2025. At the Initial Closing, we issued and sold 21,814,874 shares of common stock at a purchase price of $0.57 per share and pre-funded warrants to purchase up to 30,816,705 shares of common stock at a purchase price of $0.5699 per warrant share, the Warrant Price, to the Investors for gross proceeds to us of approximately $30.0 million. The Purchase Agreement also provides for a potential second closing for up to approximately $20.0 million in gross proceeds in exchange for up to approximately 35,087,717 shares of common stock, subject to achieving certain specified milestones related to clinical study initiation and stock price conditions or waiver thereof. For additional information, see Note 9 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K.

On March 11, 2026, we entered into a Securities Purchase Agreement, the March Purchase Agreement, with a certain institutional and accredited investor, the March Investor, pursuant to which we agreed to sell and issue shares of our common stock and a pre-funded warrant to purchase shares of common stock, the March Private Placement. The initial closing of the March Private Placement occurred on March 13, 2026. At the Closing, we issued and sold 1,179,508 shares of common stock at a purchase price of $1.854 per share and a pre-funded warrant to purchase up to 17,698,593 shares at a purchase price of $1.8539 per warrant share to the March Investor for gross proceeds to us of approximately $35.0 million.

We intend to use the net proceeds from the Private Placement and the March Private Placement to fund the further development of EQ504, working capital and general corporate purposes.

We intend to commence a Phase 1 proof-of-mechanism study for EQ504, a preclinical stage, novel AhR modulator, in mid-2026, with data expected to follow approximately six months thereafter; provided, however, we cannot provide any assurances that we will be able to obtain data within those time frames or that the data which may be obtained will be favorable to the further clinical development of EQ504. Modulation of AhR, in multiple translational models, has been shown to have a therapeutically beneficial impact inducing anti-inflammatory cells and cytokines while reducing proinflammatory cells and cytokines and improving intestinal barrier function and repair. We initially intend to develop EQ504 for the treatment of ulcerative colitis, or UC, and other gastrointestinal, or GI, diseases with potential indication expansion opportunities for the treatment of inflammatory lung diseases. We acquired the exclusive worldwide rights to EQ504 through the acquisition of Ariagen, Inc., or Ariagen, in October 2024.

We acquired the exclusive worldwide rights to EQ302 and a proprietary platform for discovering additional, novel multi-cytokine targeting product candidates, such as EQ302, through the acquisition of Bioniz Therapeutics, Inc., or Bioniz, in February 2022. That product discovery platform can be leveraged to design novel peptides to target and inhibit multiple cytokines that are involved in validated biological and disease pathways.

EQ302 is a preclinical-stage, first-in-class, selective, bi-specific inhibitor of IL-15 and IL-21 formulated for oral delivery. Inhibiting IL-15 and IL-21 is believed to be an effective treatment approach for certain GI indications, including celiac disease. Preclinical and translational data has shown that EQ302 is a potent inhibitor of those two cytokines and is stable and permeable in the gut. Based on the unique mechanism of action of EQ302 and its product profile, including the advantage of oral delivery, we believe that EQ302 has the potential to be an attractive therapeutic option for GI diseases, such as celiac disease. We are evaluating further advancement of EQ302, including product manufacturing and toxicology studies capable of supporting a potential IND filing and a first-in-human clinical study.

On September 30, 2025, the Termination Date, we entered into a termination agreement with Biocon Limited, Biocon and the agreement, the Termination Agreement, pursuant to which we terminated that certain (i) collaboration and license agreement with Biocon, dated May 22, 2017, as amended September 28, 2018, April 22, 2019, December 10, 2019, and April 14, 2021 (the Biocon License), (ii) the Memorandum of Understanding dated April 7, 2022, the MoU, and (iii) certain other corresponding agreements, collectively with the Biocon License and MoU, the Biocon Agreements, with all licenses granted by Biocon to us under the Biocon Agreements, including with respect to itolizumab, terminating and reverting to Biocon. As consideration for certain technical services that we were obligated to provide to Biocon following the Termination Date, Biocon agreed to pay us a technical service fee of $0.4 million. In lieu of Biocon paying the technical service fee to us, Biocon agreed to set off amounts which we owed to Biocon under or in connection with the Biocon Agreements through the Termination Date, with the amount of such set-off to equal such technical service fee, plus any other amount that have been or may be invoiced by us to Biocon for work performed by us with respect to itolizumab through the Termination Date, and to be limited to the aggregate amounts that have been or may be invoiced by Biocon to us, or are or may be otherwise owed to Biocon, under or in connection with the Biocon Agreements through the Termination Date. We completed our performance obligations under the Termination Agreement in the fourth quarter of 2025, resulting in the set off of amounts owed by us to Biocon totaling $0.4 million which was recorded as a reduction of research and development expense in our consolidated statement of operations in the year ended December 31, 2025.

Since our inception, substantially all of our efforts have been focused on organizing and staffing our company, business planning, raising capital, in-licensing product rights, conducting preclinical development, filing INDs, conducting clinical development, conducting CMC and formulation development activities, conducting business development activities and the general and administrative activities associated with operating a public biotech company focused on advancing novel therapeutics. We have generated revenue from our Asset Purchase Agreement with Ono, related to a one-time, upfront payment from Ono in exchange for an exclusive option to acquire our rights to itolizumab (EQ001), or the Option, as well as from itolizumab (EQ001) development funding from Ono. Ono made a strategic business decision to allow its Option to expire on October 30, 2024 and, as a result, the Asset Purchase Agreement automatically terminated on that date pursuant to its terms. We have not generated any revenue from product sales, milestone payments or royalties. Since inception, we have primarily financed our operations through debt and equity financings and revenue generated from the Asset Purchase Agreement.

We have incurred losses since our inception. For the years ended December 31, 2025 and 2024, our net losses were $22.4 million and $8.1 million, respectively. As of December 31, 2025, we had an accumulated deficit of $216.2 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 operating losses into the foreseeable future. We anticipate our expenses will increase substantially as we advance our research and development activities for EQ504, potentially pursue any future development of EQ302, potentially expand the indications for which we conduct clinical development of our product candidates, potentially acquire or develop new product candidates, including preclinical drug candidates identified through our multi-cytokine targeting drug discovery platform, seek regulatory approval for and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, and incur general corporate costs. We expect that our existing cash and cash equivalents as of December 31, 2025 plus the gross proceeds from the March Private Placement will enable us to fund our operations into 2029.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for EQ504, EQ302, or any future product candidate, which is unlikely to happen within the next 12 months, if ever. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements. However, we may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. As a result of the conflict between Russia and Ukraine, the conflict in the Middle East, government shutdowns, bank failures, tariffs, inflationary pressures on the economy and monetary policy responses by

government agencies and other macroeconomic factors, the global credit and financial markets have experienced extreme volatility, including from diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth and uncertainty about economic stability. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Financial Overview

Revenue

To date, we have not generated any revenues from therapeutic product sales, developmental milestones or royalties. In 2022, 2023 and 2024, our revenues were derived from an upfront payment under the Asset Purchase Agreement as well as from development funding from Ono. In the future, we may generate revenue from collaboration or license agreements we may enter into with respect to our product candidates, as well as product sales from any approved product, which approval is unlikely to happen within the next 12 months, if ever. Our ability to generate product revenues will depend on the successful development and eventual commercialization of EQ504 and any future product candidates. If we fail to complete the development of EQ504, or any future product candidates in a timely manner, or to obtain regulatory approval for our product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected.

Asset Purchase Agreement with Ono Pharmaceutical Co., Ltd.

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

We were responsible for conducting all research and development of itolizumab, which was funded by Ono on a quarterly basis from July 1, 2022, through October 30, 2024, the end of the option period. On October 30, 2024, the option period expired and the Asset Purchase Agreement automatically terminated pursuant to its terms.

As of December 31, 2024, there was no further deferred revenue related to the Asset Purchase Agreement.

Research and Development Expenses

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

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

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

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

Equillium Australia Pty Ltd, or Equillium Australia, a wholly-owned subsidiary of Equillium, Inc., is eligible under the Australian Research and Development Tax Incentive Program, or the Tax Incentive, to obtain a cash refund from the Australian Taxation Office, or ATO, for eligible research and development expenditures. The cash refund is received by Equillium Australia, upon filing of a claim in connection with Equillium Australia's annual income tax return. The Tax Incentive is a self-assessed program whereby Equillium Australia must assess its eligibility each year to determine (i) if the entity is eligible, (ii) if the specific research and development activities are eligible and (iii) if the individual research and development expenditures have nexus to such research and development activities. Equillium Australia evaluates its eligibility under the Tax Incentive as of each balance sheet date based on the most current and relevant data available. Equillium Australia is able to continue to claim the Tax Incentive for as long as it remains eligible and continues to incur eligible research and development expenditures. The estimated Tax Incentive refund amounts are recognized as a reduction to research and development expense when there is reasonable assurance that the Tax Incentive refund amounts will be received, the relevant expenditure has been incurred, and the amount can be reliably measured.

We plan to continue to incur substantial research and development expenses for the foreseeable future as we advance the development of EQ504, and potentially EQ302, potentially expand the number of indications for which we are developing those product candidates, and potentially acquire or develop new product candidates. The successful development of EQ504 and EQ302 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 our product candidates or the period, if any, in which material net cash inflows from the sales from our product candidates may commence. Clinical development timelines, the probability of success, and development costs can differ materially from expectations.

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

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

General and Administrative Expenses

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

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

Interest Income

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

Other Income (Expense), Net

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

Income Tax Expense

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

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table sets forth our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Revenue	$ -	$ 41,095	$ (41,095)
Research and development	12,843	37,428	(24,585)
General and administrative	10,791	11,936	(1,145)
Interest income	833	1,381	(548)
Other income (expense), net	403	(818)	1,221
Income tax expense	-	361	(361)

Revenue

During the year ended December 31, 2025, there was no revenue recognized under our Asset Purchase Agreement with Ono. During the year ended December 31, 2024, we recognized revenue of $41.1 million under our Asset Purchase Agreement with Ono. For the year ended December 31, 2024, development funding represented $28.3 million and amortization of the upfront payment represented $12.8 million.

Research and Development Expenses

	Year Ended December 31,		
	2025	2024	Change
Direct external expenses:			
Itolizumab (EQ001) - EQUATOR	$ 4,827	$ 22,490	$ (17,663)
Itolizumab (EQ001) - EQUALISE	52	749	(697)
Itolizumab - Biocon ulcerative colitis study - related party	(115)	602	(717)
EQ101	117	1,528	(1,411)
EQ102	21	403	(382)
EQ504	1,301	784	517
EQ302	110	584	(474)
Indirect expenses:			
Employee compensation and benefits (including stock-based compensation)	5,483	8,579	(3,096)
Overhead	1,047	1,709	(662)
Total research and development	$ 12,843	$ 37,428	$ (24,585)

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We separate our research and development costs into two broad categories: direct and indirect. Additionally, with respect to direct research and development expenses, we further divide expenses into the following product candidate categories: Itolizumab (EQ001), EQ101, EQ102, EQ504 and EQ302. Itolizumab (EQ001) includes sub-categories for the clinical studies associated with itolizumab (EQ001) including our EQUATOR, EQUALISE and UC study with Biocon. For direct research and development expenses, we track specific project research and development expenses that are directly attributable to our preclinical and clinical development product candidates that have been selected for further development. Such direct research and development expenses include nonclinical and clinical trial activities, external expenses related to CMC and supply of drug product and consulting expenses.

All remaining research and development expenses are categorized as indirect research and development expenses. Such indirect research and development expenses include employee compensation and benefits (including stock-based compensation expenses) and general overhead costs such as costs associated with our facilities and lab supplies. These expenses are not directly tied to any individual product candidate or clinical study and are generally deployed across multiple studies. As such, we do not maintain information regarding those costs incurred on an individual product candidate or clinical study basis.

Research and development expenses were $12.8 million for the year ended December 31, 2025, compared to $37.4 million for the year ended December 31, 2024.

Research and development expenses decreased by $24.6 million for the year ended December 31, 2025. Direct external expenses decreased significantly for the year ended December 31, 2025 compared to the same period in 2024 due to the wind down of our clinical studies in 2025 including lower clinical development expenses, lower CMC activities with Biocon and lower consulting expenses primarily related to the wind down of our EQUATOR study. In addition, we negotiated discounts with our clinical vendors on outstanding accounts payable which were recorded as a reduction to research and development expense during the year ended December 31, 2025. Indirect expenses decreased for the year ended December 31, 2025 compared to the same period in 2024 driven by lower employee compensation and benefits due to lower headcount caused by the wind down of our clinical studies.

We expect research and development expenses in future periods to increase primarily due to the advancement of EQ504, our novel AhR modulator, into and through clinical development.

General and Administrative Expenses

General and administrative expenses were $10.8 million for the year ended December 31, 2025, compared to $11.9 million for the year ended December 31, 2024.

The decrease of $1.1 million in general and administrative expenses for the year ended December 31, 2025, compared to the same period in 2024, was primarily related to decreases of (i) $0.6 million in overhead primarily due to lower franchise taxes, directors and officers insurance costs and travel and (ii) $0.5 million in legal expenses.

Interest Income

Interest income was $0.8 million for the year ended December 31, 2025, compared to $1.4 million for the year ended December 31, 2024. The decrease in interest income was primarily due to lower average cash, cash equivalents and short-term investment balances in 2025 compared to 2024.

Other Income (Expense), Net

Other income (expense), net was other income of $0.4 million for the year ended December 31, 2025, compared to other expense of $0.8 million for the year ended December 31, 2024. The change in other income (expense), net for the year ended December 31, 2025, compared to the same period in 2024, was primarily due to fluctuations in net foreign currency transaction unrealized gains and losses.

Income Tax Expense

There was no income tax expense for the year ended December 31, 2025. Income tax expense was $0.4 million for the year ended December 31, 2024. Our 2024 income tax expense was primarily attributable to domestic cash tax expense resulting from differences between book and tax treatment of certain items. We do not record a deferred tax provision as there is a full valuation allowance offsetting our deferred tax assets.

Liquidity and Capital Resources

From inception through December 31, 2025, we have financed our operations primarily through the sale of equity and debt securities and income generated from our Asset Purchase Agreement with Ono as described in more detail in the Sources of Liquidity section below. As of December 31, 2025, we had an accumulated deficit of $216.2 million and anticipate that we will continue to incur net losses for the foreseeable future. As of December 31, 2025, we had $30.3 million in cash and cash equivalents, excluding the gross proceeds of approximately $35.0 million from the Company's equity financing in March 2026.

Sources of Liquidity

August Securities Purchase Agreement

On August 10, 2025, we entered into the Purchase Agreement with the Investors, pursuant to which we agreed to sell and issue shares of our common stock, par value $0.0001, and pre-funded warrants to purchase shares of common stock, in up to two closings in the Private Placement.

The Initial Closing of the Private Placement occurred on August 12, 2025. At the Initial Closing, we issued and sold 21,814,874 shares of common stock at a purchase price of $0.57 per share and pre-funded warrants to purchase up to 30,816,705 shares of common stock at a purchase price of $0.5699 per warrant share, the Warrant Price, to the Investors for gross proceeds to us of approximately $30.0 million. Net proceeds from the Private Placement were $27.9 million, after deducting placement agent fees and offering expenses totaling $2.1 million.

The Purchase Agreement also provides for a potential second closing for up to approximately $20.0 million in gross proceeds in exchange for up to approximately 35,087,717 shares of common stock, subject to achieving certain specified milestones related to clinical study initiation and stock price conditions or waiver thereof. There can be no assurance that the specified milestones will be met or that the investors will purchase additional shares of common stock or pre-funded warrants in a second closing. For additional information, see Note 9 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K.

2023 ATM Facility

In October 2023, we entered into an at-the-market facility with Jefferies LLC, or Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $21.95 million from time to time through Jefferies acting as our sales agent, or the 2023 ATM Facility. There were no shares sold under the 2023 ATM Facility from October

2023 through December 31, 2024. In March 2025, there were 109,410 shares sold under the 2023 ATM Facility for gross proceeds of $55,000. Issuance costs related to the 2023 ATM Facility totaled $0.5 million through March 31, 2025.

On August 3, 2025, we entered into Amendment No. 1 to the 2023 ATM Facility pursuant to which Jefferies was replaced by LifeSci Capital LLC as the sales agent under the 2023 ATM Facility. During the year ended December 31, 2025, there were 1,610,075 shares of common stock sold under the 2023 ATM Facility, as amended, for gross proceeds of approximately $0.9 million. During the year ended December 31, 2025, issuance costs related to the 2023 ATM Facility, as amended, totaled $0.2 million.

On September 19, 2025, we filed a prospectus supplement with the SEC under which we may offer and sell shares of our common stock having an aggregate offering price of up to $75.0 million, pursuant to the 2023 ATM Facility, as amended.

As of December 31, 2025 and through the date of the filing of this Annual Report on Form 10-K, there were no additional shares of common stock sold under the 2023 ATM Facility, as amended.

March Securities Purchase Agreement

On March 11, 2026, we entered into the March Purchase Agreement with the March Investor, pursuant to which we agreed to sell and issue shares of our common stock, par value $0.0001, and a pre-funded warrant to purchase shares of common stock. The closing of the March Private Placement occurred on March 13, 2026. At the closing, we issued and sold 1,179,508 shares at a purchase price of $1.854 per share and a pre-funded warrant to purchase up to 17,698,593 shares at a purchase price of $1.8539 per warrant share to the March Investor for gross proceeds to us of approximately $35.0 million.

Funding Requirements

We expect our expenses to increase substantially as we advance our research and development activities, including resuming development of our preclinical asset, EQ504 and potentially resuming development of EQ302. We expect that our primary uses of capital will be for nonclinical research, clinical development, CMC activities, formulation development, product supply, potential acquisition of new products, legal and other regulatory compliance expenses, employee compensation and related expenses, insurance premiums, working capital and other general overhead costs.

We believe that our cash and cash equivalents as of December 31, 2025 plus with proceeds from the March Private Placement can fund operations into 2029. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Furthermore, our operating plans may change, and we may need additional funds sooner than planned. Additionally, the process of testing product candidates in clinical studies is costly, and the timing of progress in these studies is uncertain. Because the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of EQ504 and EQ302, or any of our other product candidates or whether, or when, we may achieve profitability.

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

- the initiation, progress, timing, costs and results of our planned or future nonclinical and clinical studies of EQ504 and EQ302 and other future product candidates, including as such activities may be adversely impacted by public health epidemics or outbreaks, the evolving conflict between Russia and Ukraine, the conflict in the Middle East, bank failures, tariffs and inflationary pressures on the economy;
- the advancement and cost of preclinical research of EQ504, EQ302 and other novel preclinical drug candidates;
- the number and scope of indications we decide to pursue for the development of our product candidates;
- the cost, timing and outcome of regulatory review of any NDA we may submit for our product candidates;
- the costs and timing of manufacturing EQ504 and other product candidates;
- the costs of drug formulation research and device development;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;

- our ability to enter into partnerships or otherwise monetize our pipeline through strategic transactions on a timely basis, on terms that are favorable to us, or at all;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies or engage in in-house discovery and preclinical research of new product candidates;
- the legal and other transactional costs associated with our business development activities; and
- the cost associated with commercializing EQ504 or any of our other product candidates, if approved for commercial sale.

Until such time as we can generate product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements. The sale of additional equity or convertible debt could result in additional dilution to our stockholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. The incurrence of debt financing would result in debt service obligations and the governing documents would likely include operating and financing covenants that would restrict our operations. As a result of the conflict between Russia and Ukraine, the conflict in the Middle East, government shutdowns, bank failures, tariffs, inflationary pressures on the economy and monetary policy responses taken by government agencies and other macroeconomic factors, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we raise additional funds through collaboration or license agreements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations. Any of these actions could have a material effect on our business, financial condition and results of operations. We have experienced net losses and negative cash flows from operating activities since our inception and expect to continue to incur net losses into the foreseeable future. We had an accumulated deficit of $216.2 million as of December 31, 2025. We expect operating losses and negative cash flows to continue for at least the next several years as we incur costs related to the development of EQ504, EQ302 and any of our other product candidates.

Material Cash Requirements

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

Cash Flows

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

	Year Ended December 31,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ (22,746)	$ (19,026)
Investing activities	4,464	13,814
Financing activities	30,427	164
Effect of exchange rate changes on cash	47	(83)
Net increase (decrease) in cash and cash equivalents	$ 12,192	$ (5,131)

Operating Activities

During the year ended December 31, 2025, cash used in operating activities was $22.7 million compared to $19.0 million during the year ended December 31, 2024. Cash used in operating activities during the year ended December 31, 2025 primarily related to our net loss of $22.4 million, adjusted for non-cash items of $2.0 million, primarily consisting of non-cash stock-based compensation expenses, and net cash outflows from changes in other operating assets and liabilities of $2.3 million. Cash used in operating activities during the year ended December 31, 2024 primarily related to our net loss of $8.1 million, adjusted for non-cash items of $3.9 million, primarily consisting of non-cash stock-based compensation expenses, and net cash outflows from changes in deferred revenue and other operating assets and liabilities of $14.9 million.

Investing Activities

Net cash provided by investing activities was $4.5 million during the year ended December 31, 2025 and primarily consisted of maturities of our short-term investments.

Net cash provided by investing activities was $13.8 million during the year ended December 31, 2024. Maturities of our short-term investments totaled $31.5 million, which was offset by purchases of short-term investments totaling $17.6 million during the period. Purchases of property and equipment for the year ended December 31, 2024 totaled $0.1 million.

Financing Activities

Net cash provided by financing activities totaled $30.4 million during the year ended December 31, 2025 and primarily consisted of net proceeds from the sale of shares under the Private Placement transaction totaling $27.9 million, proceeds totaling $1.8 million from the exercise of stock options and net proceeds from the sale of shares under our 2023 ATM Facility totaling approximately $0.7 million.

Net cash provided by financing activities totaled $0.2 million during the year ended December 31, 2024 and was primarily attributed to cash received from employee stock purchases related to our Employee Stock Purchase Plan.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

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

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 nonclinical study or clinical study as measured by the timing of various aspects of the study or related activities. We determine accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study or clinical study, we adjust our rate of expense recognition if actual results differ from our estimates.

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

Stock-based Compensation Expense

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

Recent Accounting Pronouncements

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

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

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

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

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

Not applicable.

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, 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, 2025, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act. Based on this evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Report on Internal Control over Financial Reporting

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

As of December 31, 2025, 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, 2025, 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, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Trading Arrangements

During the three months ended December 31, 2025, an officer (as defined in Rule 16a-1(f) under the Exchange Act) adopted a contract, instruction or written plan for the sale of our securities set forth in the table below:

Name and Position	Action	Adoption/Termination Date	Type of Trading Arrangement		Total Shares of Common Stock to be Sold	Expiration Date
			Rule 10b5-1[1]	Non-Rule 10b5-1[2]		
Penny Tom, SVP Finance & Principal Accounting Officer	Adoption[3]	October 10, 2025	X		351,948	October 10, 2026

[1] Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.
[2] "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.
[3] Represents the adoption of a written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) adopted on December 12, 2023.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this item will be contained in our definitive proxy statement, or the Proxy Statement, to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2025, under the sections entitled "Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," "Information Regarding Committees of the Board of Directors," "Executive Officers" and is incorporated in this Annual Report on Form 10-K by reference.

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

We have adopted insider trading policies and procedures governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees that are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our insider trading policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

Item 11. Executive Compensation.

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

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

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

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

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

Item 14. Principal Accountant Fees and Services.

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

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Consolidated Financial statements:

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

(a)(2) Financial Statement Schedules:

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

(a)(3) Exhibits

Exhibit Index

Exhibit Number	Description
2.1†††*	Agreement and Plan of Merger, dated February 14, 2022, by and among Registrant, Bioniz Therapeutics, Inc., Project JetFuel Merger Sub, Inc. and Kevin Green, solely in his capacity as Securityholders' Representative, incorporated by reference by Exhibit 2.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 16, 2022.
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on October 16, 2018.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 16, 2018.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
4.2	Warrant to Purchase Common Stock, dated September 30, 2019, issued to Oxford Valley Finance LLC, incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2019.
4.3	Warrant to Purchase Common Stock, dated September 30, 2019, issued to Silicon Valley Bank, incorporated by reference to Exhibit 4.3 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2019.
4.4	Description of Common Stock, incorporated by reference to Exhibit 4.4 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
4.5†	Registration Rights Agreement, dated August 12, 2025, by and between the Registrant and the investors named therein, incorporated by reference to Exhibit 4.5 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 14, 2025.
4.6	Form of Pre-Funded Warrant to Purchase Common Stock, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 11, 2025.
4.7	Form of Pre-Funded Warrant to Purchase Common Stock, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 13, 2026.
4.8	Registration Rights Agreement, dated March 13, 2026, by and between the Registrant and the investor named therein, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 13, 2026.
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, Inc. 2018 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise, as amended, incorporated by reference to Exhibit 99.1 of the Registrant's Registration Statement on Form S-8 (File No. 333-290140), filed with the Securities and Exchange Commission on September 9, 2025.
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+	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.
10.6+	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.
10.7+	Offer Letter, dated January 19, 2018, by and between the Registrant and Christine Zedelmayer, incorporated by reference to Exhibit 10.19 of the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2020.
10.8+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Bruce D. Steel, incorporated by reference to Exhibit 10.22 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
10.9+	First Amendment to Offer Letter, effective as of January 1, 2020, by and between the Registrant and Christine Zedelmayer, incorporated by reference to Exhibit 10.23 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 26, 2020.
10.10	Open Market Sale Agreement, dated as of October 5, 2023, by and between the Registrant and LifeSci Advisors LLC, as amended by Amendment No. 1 dated August 3, 2025, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 4, 2025.
10.11+	Equillium, Inc. Non-Employee Director Compensation Policy, as amended and restated, effective March 2, 2026.
10.12+	Equillium, Inc. 2024 Inducement Plan and Forms of Stock Option Grant Notice, Option Agreement, and Notice of Exercise thereunder, incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 8, 2024.
10.13†	Stock Purchase Agreement, dated October 4, 2024, by and among Registrant, Ariagen, Inc., the stockholders of Ariagen and the securityholder representative, incorporated by reference to Exhibit 10.24 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 27, 2025.
10.14†	Securities Purchase Agreement, dated August 10, 2025, by and among Company and the Investors, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 11, 2025.
10.15†	Securities Purchase Agreement, dated March 11, 2026, by and between the Company and the Investor, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 13, 2026.
19.1	Insider Trading Policy, as amended.
21.1	Subsidiaries of Equillium, Inc.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	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 and Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended.

32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Securities Exchange Act, as amended, and 18 U.S.C. Section 1350.
97.1	Incentive Compensation Recoupment Policy, incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 25, 2024.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

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

+ Indicates management contract or compensatory plan.

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

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

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

EQUILLIUM, INC.

Date: March 25, 2026

By: /s/ Bruce D. Steel

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bruce D. Steel 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	Chief Executive Officer and Member of the Board of Directors *(Principal Executive Officer and Principal Financial Officer)*	March 25, 2026
/s/ Penny Tom Penny Tom	Senior Vice President, Finance *(Principal Accounting Officer)*	March 25, 2026
/s/ Daniel M. Bradbury Daniel M. Bradbury	Chairman of the Board of Directors	March 25, 2026
/s/ Peter Colabuono Peter Colabuono	Member of the Board of Directors	March 25, 2026
/s/ Martha J. Demski Martha J. Demski	Member of the Board of Directors	March 25, 2026
/s/ Charles McDermott Charles McDermott	Member of the Board of Directors	March 25, 2026
/s/ Mark Pruzanski, M.D. Mark Pruzanski, M.D.	Member of the Board of Directors	March 25, 2026
/s/ Barbara Troupin, M.D. Barbara Troupin, M.D.	Member of the Board of Directors	March 25, 2026

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
EQUILLIUM, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Equillium, Inc.
La Jolla, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Equillium, Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Crowe LLP

We have served as the Company's auditor since 2025.

Costa Mesa, California
March 25, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

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

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered significant operating losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

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

San Diego, California
March 27, 2025

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

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 30,277	$ 18,085
Short-term investments	-	4,490
Prepaid expenses and other current assets	761	2,403
Total current assets	31,038	24,978
Operating lease right-of-use assets	658	364
Property and equipment, net	164	262
Other assets	27	-
Total assets	$ 31,887	$ 25,604
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 755	$ 2,676
Accrued expenses	1,816	3,483
Current portion of operating lease liabilities	363	197
Total current liabilities	2,934	6,356
Long-term operating lease liabilities	356	187
Total liabilities	3,290	6,543
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2025 and 2024; 61,464,368 and 35,557,563 shares issued and outstanding as of December 31, 2025 and 2024, respectively	5	3
Additional paid-in capital	244,434	212,084
Accumulated other comprehensive income	363	781
Accumulated deficit	(216,205)	(193,807)
Total stockholders' equity	28,597	19,061
Total liabilities and stockholders' equity	$ 31,887	$ 25,604

See accompanying notes.

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

	Year Ended December 31, 2025	Year Ended December 31, 2024
Revenue	$ -	$ 41,095
Operating expenses:		
Research and development	12,843	37,428
General and administrative	10,791	11,936
Total operating expenses	23,634	49,364
Loss from operations	(23,634)	(8,269)
Other income, net:		
Interest income	833	1,381
Other income (expense), net	403	(818)
Total other income, net	1,236	563
Loss before income tax expense	(22,398)	(7,706)
Income tax expense	-	361
Net loss	$ (22,398)	$ (8,067)
Other comprehensive (loss) income, net:		
Unrealized loss on available-for-sale securities, net	(3)	(15)
Foreign currency translation (loss) gain	(415)	656
Total other comprehensive (loss) income, net	(418)	641
Comprehensive loss	$ (22,816)	$ (7,426)
Net loss per share, basic and diluted	$ (0.39)	$ (0.23)
Weighted-average number of common shares outstanding, basic and diluted	57,304,181	35,357,641

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, 2023	35,254,752	$ 3	$ 208,170	$ 140	$ (185,740)	$ 22,573
Issuance of common stock under employee stock purchase plan	296,436	-	160	-	-	160
Exercise of stock options	6,375	-	4	-	-	4
Stock-based compensation expense	-	-	3,750	-	-	3,750
Other comprehensive income	-	-	-	641	-	641
Net loss	-	-	-	-	(8,067)	(8,067)
Balance at December 31, 2024	35,557,563	$ 3	$ 212,084	$ 781	$ (193,807)	$ 19,061
Issuance of common stock under ATM, net of issuance costs	1,719,485	-	290	-	-	290
Issuance of common stock and pre-funded warrants in a private placement, net of issuance costs	21,814,874	2	27,907	-	-	27,909
Exercise of stock options	2,372,446	-	1,831	-	-	1,831
Stock-based compensation expense	-	-	2,322	-	-	2,322
Other comprehensive loss	-	-	-	(418)	-	(418)
Net loss	-	-	-	-	(22,398)	(22,398)
Balance at December 31, 2025	61,464,368	$ 5	$ 244,434	$ 363	$ (216,205)	$ 28,597

See accompanying notes.

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

	Year Ended December 31, 2025	Year Ended December 31, 2024
Operating activities:		
Net loss	$ (22,398)	$ (8,067)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	116	137
Loss on disposal of property and equipment	19	-
Stock-based compensation	2,322	3,750
Net unrealized (gain) loss on foreign currency transactions	(474)	794
Amortization of investments, net	(14)	(754)
Deferred revenue	-	(15,728)
Changes in operating assets and liabilities:		
Accounts receivable	-	3,735
Prepaid expenses and other current assets	1,263	2,275
Accounts payable	(1,937)	(1,995)
Accrued expenses	(1,685)	(3,164)
Right-of-use assets and lease liabilities, net	42	(9)
Net cash used in operating activities	(22,746)	(19,026)
Investing activities:		
Purchases of property and equipment	(48)	(85)
Proceeds from disposal of property and equipment	12	-
Purchases of short-term investments	-	(17,601)
Maturities of short-term investments	4,500	31,500
Net cash provided by investing activities	4,464	13,814
Financing activities:		
Proceeds from a private placement of common stock and pre-funded warrants, net of issuance costs	27,909	-
Proceeds from exercise of stock options	1,836	4
Proceeds from issuance of common stock under ATM facility, net of issuance costs	682	-
Proceeds from issuance of common stock under employee stock purchase plan	-	160
Net cash provided by financing activities	30,427	164
Effect of exchange rate changes on cash and cash equivalents	47	(83)
Net increase (decrease) in cash and cash equivalents	12,192	(5,131)
Cash and cash equivalents at beginning of period	18,085	23,216
Cash and cash equivalents at end of period	$ 30,277	$ 18,085
Non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 548	$ -
ATM facility issuance costs reclassed from other current assets	$ 392	$ -
Exercise of stock options issuance costs in accounts payable	$ 5	$ -
Supplemental cash flow information:		
Cash paid for income taxes, net of refunds	$ 352	$ -

See accompanying notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Accounting Pronouncements

Description of Business

Equillium, Inc., together with its wholly owned subsidiaries (the Company), was incorporated in the state of Delaware on March 16, 2017.

The Company is a biotechnology innovator developing novel therapies to treat severe autoimmune and inflammatory disorders with the mission to develop life-changing therapeutics for patients. The Company's primary goal is to advance EQ504, its novel aryl hydrocarbon receptor modulator, into and through clinical development.

The Company is headquartered in La Jolla, California, and it manages its business as one operating segment. Refer to Note 14 for additional information.

Liquidity and Business Risks

As of December 31, 2025, the Company had $30.3 million in cash and cash equivalents, excluding the gross proceeds of approximately $35.0 million from the Company's equity financing in March 2026. From inception through December 31, 2025, substantially all of the Company’s efforts have been focused on research, development and the advancement of the Company’s clinical and preclinical product candidates. The Company has not yet generated product sales and as a result has incurred significant operating losses and negative cash flows from operations. As a result, the Company has an accumulated deficit of $216.2 million as of December 31, 2025. The Company expects to incur additional losses in the future to conduct research and development for which it will need to raise additional capital to implement.

During the third quarter of 2025, the Company completed an equity financing with gross proceeds of approximately $30 million with the ability to raise an additional $20 million subject to achieving certain clinical and pricing related milestones. Refer to Note 9 for additional information. In March 2026, the Company completed an equity financing with gross proceeds of approximately $35.0 million. Refer to Note 15 for additional information. Management believes that the Company's cash and cash equivalents will be sufficient to fund operations for at least the next 12 months from the date this Annual Report on Form 10-K is filed with the Securities and Exchange Commission (SEC).

Basis of Presentation

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

Principles of Consolidation

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

Foreign Currency Translation

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

Recently Issued and Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 requires annual disclosures of specific categories in the rate reconciliation, additional information for reconciling items that meet a quantitative threshold and a disaggregation of income taxes paid, net of refunds. ASU 2023-09 also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities. ASU 2023-09 is effective for the Company beginning with the Company's Annual Report on Form 10-K for the year ended December 31, 2025. Early adoption is permitted. ASU 2023-09 should be applied prospectively. Retrospective adoption is permitted. The Company adopted ASU 2023-09 during the year ended December 31, 2025, on a prospective

basis. The adoption did not have a material impact on the Company's consolidated financial statements, as the amendments relate to disclosure requirements only. See Note 11 for more information on the effects of the adoption of ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses,* to improve disclosures around an entity's expenses. Upon adoption, companies will be required to disclose in the notes to the financial statements a disaggregation of certain expense categories included within the expense captions on the face of the income statement. The standard is effective for annual reporting periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027, with early adoption permitted, and can be applied either prospectively or retrospectively. The Company plans to adopt the standard in its 2027 annual period and is currently assessing the impact this standard will have on the Company's consolidated financial statement disclosures.

No other new accounting pronouncements or legislation issued or effective as of December 31, 2025 have had, or are expected to have, a material impact on the Company’s consolidated financial statements.

2. Summary of Significant Accounting Policies

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the business of developing novel therapies to treat severe autoimmune and inflammatory disorders with the mission to develop life-changing therapeutics for patients. See Note 14 for more information on the Company's segment reporting.

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, revenues and expenses and the disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Significant estimates in the Company’s consolidated financial statements relate to accrued research and development expenses, revenue recognition and the valuation of equity awards. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company’s historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company’s investment policy includes guidelines for the quality of the related institutions and financial instruments and defines allowable investments that the Company may invest in, which the Company believes minimizes the exposure to concentration of credit risk.

Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation gains and losses. Other comprehensive (loss) income, net includes unrealized gains or losses on short-term investments as well as foreign currency translation gains or losses.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking and savings accounts, and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. At December 31, 2025 and 2024, the Company's cash and cash equivalents were primarily comprised of money market funds.

Short-Term Investments

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive loss. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2025	2024
Australian research and development tax incentive	$ -	$ 966
Other current assets	214	429
Prepaid insurance	295	426
Prepaid other	144	369
Other receivables	108	178
Prepaid clinical development	-	35
Total prepaid expenses and other current assets	$ 761	$ 2,403

Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to five years).

Leases

The Company determines if an arrangement is a lease at inception. Lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. For operating leases with an initial term greater than 12 months, the Company recognizes operating lease right-of-use assets and operating lease liabilities based on the present value of lease payments over the lease term at the commencement date. Operating lease right-of-use assets are comprised of the lease liability plus any lease payments made and excludes lease incentives. Lease terms include options to renew or terminate the lease when the Company is reasonably certain that the renewal option will be exercised or when it is reasonably certain that the termination option will not be exercised. For the Company's operating leases, if the interest rate used to determine the present value of future lease payments is not readily determinable, the Company estimates its incremental borrowing rate as the discount rate for the lease. The Company's incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, and in similar economic environments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has elected the practical expedient to not separate lease and non-lease components.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company’s current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since inception.

Accrued Research and Development Expense

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

Australian Research and Development Tax Incentive

Equillium Australia Pty Ltd (Equillium Australia), a wholly-owned subsidiary of Equillium, Inc., is eligible under the Australian Research and Development Tax Incentive Program (the Tax Incentive) to obtain a cash refund from the Australian Taxation Office (ATO) for eligible research and development expenditures. The cash refund is received by Equillium Australia upon filing of a Tax Incentive claim in connection with Equillium Australia's annual income tax return.

The Tax Incentive is a self-assess program whereby Equillium Australia must assess each year (i) if the entity is eligible, (ii) if the specific research and development activities are eligible and (iii) if the individual research and development expenditures have nexus to such research and development activities. Equillium Australia evaluates its eligibility under the Tax Incentive as of each balance sheet date based on the most current and relevant data available. Equillium Australia is able to continue to claim refunds under the Tax Incentive for as long as it remains eligible and continues to incur eligible research and development expenditures.

Although Equillium Australia believes that it has complied with all relevant conditions of eligibility under the program for all periods claimed, the ATO has the right to review Equillium Australia's qualifying programs and related expenditures for a period of up to four years. Additionally, the period open for review is indefinite if the ATO suspects fraud. If such a review were to occur, the ATO may have different interpretations of certain eligibility requirements. If the ATO disagreed with Equillium Australia's assessments and any related subsequent appeals, it could require adjustment to and potential repayment of current or previous years' claims already received. If Equillium Australia was unable to demonstrate a reasonably arguable position taken on such claims, the ATO could also assess penalties and interest on potential adjustment amounts. The Company has not provided any allowance for any such potential adjustments, should they occur in the future.

The estimated Tax Incentive refund amounts are recognized as a reduction to research and development expense when there is reasonable assurance that the Tax Incentive refund amounts will be received, the relevant expenditure has been incurred, and the amount can be reliably measured. During the year ended December 31, 2025, the Company did not record a reduction to research and development expenses related to the Tax Incentive due to the substantial completion of its EQ101 and EQ102 clinical trials in Australia. During the year ended December 31, 2024, the Company recorded $1.7 million as a reduction to research and development expenses related to the Tax Incentive. The Company classifies its estimate for the Tax Incentive as prepaid expenses and other current assets on the accompanying consolidated balance sheets. As of December 31, 2025, there were no amounts recorded within prepaid and other current assets attributed to the Tax Incentive. As of December 31, 2024, the Company recorded $1.0 million within prepaid and other current assets attributed to the Tax Incentive.

Distinguishing Liabilities from Equity

The Company evaluates equity or liability classification for freestanding financial instruments, including warrants and options, pursuant to the guidance under ASC Topic 480, *Distinguishing Liabilities from Equity* (ASC 480). The Company classifies as liabilities all freestanding financial instruments that are (i) mandatorily redeemable, (ii) represent an obligation to repurchase the Company's equity shares by transferring assets, or (iii) represent an unconditional obligation (or conditional obligation if the financial instrument is not an outstanding share) to issue a variable number of shares predominantly based on a fixed monetary amount, variations in something other than the fair value of the Company's equity shares, or variations inversely related to changes in fair value of the Company's equity shares.

If a freestanding financial instrument does not represent an outstanding equity share and does not meet liability classification under ASC 480, the Company then assesses whether the freestanding financial instrument is indexed to its own stock and meets equity classification pursuant to ASC 815-40, *Derivatives and Hedging* (ASC 815). The Company further assesses whether the freestanding financial instruments should be classified as temporary equity. Freestanding financial instruments that are redeemable for cash or other assets at a fixed or determinable date, at the option of the holder, or upon the occurrence

of an event are classified in temporary equity in accordance with ASC 480. Otherwise, the freestanding financial instruments are classified in permanent equity.

See Note 9, Stockholders' Equity, for additional information on the freestanding financial instruments assessed under ASC 480 and ASC 815-40 for equity or liability classification.

Revenue Recognition

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

Research and Development

Research and development expenses include salaries and related overhead expenses, non-cash stock-based compensation expense, external research and development expenses incurred under arrangements with third parties, costs of services performed by consultants and contract research organizations, and regulatory costs including those related to preparing and filing INDs with the FDA. Research and development costs are expensed as incurred.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the consolidated statement of operations and comprehensive loss.

Stock-Based Compensation

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

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

Pursuant to the Internal Revenue Code of 1986, as amended (IRC), specifically Sections 382 and 383, the Company’s ability to use tax attribute carryforwards to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company completed an ownership change analysis through December 31, 2024 pursuant to IRC Section 382 and determined that the Company’s ability to offset taxable income in 2024 is not expected to be impacted by ownership changes occurring prior to that date. If ownership changes within the meaning of IRC Section 382 occur in the future, the amount of remaining tax attribute carryforwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, the Company's

deferred tax assets associated with such tax attributes could be significantly reduced or eliminated upon realization of an ownership change within the meaning of IRC Section 382. If eliminated, the related asset would be removed from the deferred tax asset schedule, with a corresponding reduction in the valuation allowance. Additionally, limitations on the utilization of the Company's tax attribute carryforwards can increase the amount of taxable income and current income tax expense recognized. Due to the existence of the valuation allowance, ownership change limitations that are not significant may not impact the Company's effective tax rate.

The 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 and diluted net loss per share is determined by dividing the net loss by the weighted-average number of common shares outstanding for the period. For all periods presented, the Company's potentially dilutive securities include outstanding options under the Company's 2018 Equity Incentive Plan, 2024 Inducement 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. Pre-funded warrants to purchase 30,816,705 shares of common stock are included in the computation of basic and diluted net loss per share for the year ended December 31, 2025, as the pre-funded warrants are exercisable for nominal consideration. There were no pre-funded warrants to purchase common stock in the year ended December 31, 2024. For all periods presented, there is no difference in the number of shares of common stock or common stock equivalents 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,	
	2025	2024
Common stock options	10,414,561	9,023,792
Common stock warrants	1,366,141	1,366,141
Total	11,780,702	10,389,933

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. 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, 2025	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)
Assets:				
Money Market funds (a)	$ 29,733	$ 29,733	$ -	$ -
Total assets at fair value	$ 29,733	$ 29,733	$ -	$ -

	December 31, 2024	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)
Assets:				
Money Market funds (a)	$ 14,457	$ 14,457	$ -	$ -
U.S. treasury securities (b)	4,490	4,490	-	-
Total assets at fair value	$ 18,947	$ 18,947	$ -	$ -

(a) Money Market funds included in cash and cash equivalents in the consolidated balance sheets, are valued at quoted market prices in active markets.

(b) U.S. treasury securities included in short-term investments in the consolidated balance sheet as of December 31, 2024, are recorded at fair market value, which is determined based on the most recent observable inputs for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active or are directly or indirectly observable. There were no short-term investments as of December 31, 2025.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities.

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, 2025 or 2024.

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, 2024					
U.S. treasury securities	1 or less	$ 4,487	$ 3	$ -	$ 4,490
Total		$ 4,487	$ 3	$ -	$ 4,490

The Company does not have any available-for-sale securities as of December 31, 2025. 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.

There were no impairments considered other-than-temporary during the periods presented, as it is management's intention and ability to hold the securities until a recovery of the cost basis or recovery of fair value. Unrealized gains and losses are included in accumulated other comprehensive income in the Company's consolidated balance sheets.

5. Property and Equipment

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

	December 31,	
	2025	2024
Furniture & fixtures	$ 58	$ 58
Machinery & lab equipment	656	660
Computer equipment	9	23
Leasehold improvements	3	20
Less accumulated depreciation and amortization	(562)	(499)
Property and equipment, net	$ 164	$ 262

Depreciation expense related to property and equipment was $0.1 million for each of the years ended December 31, 2025 and 2024. During the year ended December 31, 2025, the Company disposed of property and equipment with a net book value totaling $31,000 for cash proceeds of $12,000. As a result, the Company recognized a loss on disposal of property and equipment of $19,000, which is included in other income (expense), net in the consolidated statement of operations and comprehensive loss. No material gains or losses on the disposal of property and equipment were recorded for the year ended December 31, 2024.

6. Leases

In September 2025, the Company entered into a non-cancelable operating lease for laboratory space in San Diego, California which expires in January 2028. Upon lease commencement, the Company recognized a right-of-use asset and a corresponding lease liability of $0.5 million. The Company's lease for laboratory space in La Jolla, California expired in August 2025 and the Company did not renew that lease. The Company also leases office space located in La Jolla that expires in February 2027.

The terms of the Company’s non-cancelable operating lease arrangements typically contain fixed lease payments which increase over the term of the lease at fixed rates and include rent holidays and provide for additional renewal periods. Lease expense is recognized over the term of the lease on a straight-line basis. All of the Company’s leases are classified as operating leases. The Company has determined that periods covered by options to extend the Company’s leases are excluded from the lease term as the Company is not reasonably certain the Company will exercise such options. Operating lease expense, including expenses related to short-term leases, was $0.5 million for each of the years ended December 31, 2025 and 2024.

Under the lease arrangements, the Company may be required to pay directly, or reimburse the lessor for real estate taxes, insurance, utilities, maintenance and other operating costs. Such amounts are variable and therefore not included in the measurement of the right-of-use assets and related lease liability but are instead recognized as variable lease expense in the Company's consolidated statements of operations and comprehensive loss when they are incurred. Variable lease expense, including expenses related to short-term leases, was $0.3 million for each of the years ended December 31, 2025 and 2024.

The Company records its right-of-use-assets within other assets (long term) and its operating lease liabilities within other current and long-term liabilities.

Additional information related to the Company's leases as of and for the years ended December 31, 2025 and 2024 is as follows (in thousands, except lease term and discount rate):

	December 31, 2025	December 31, 2024
Balance sheet information		
Right-of-use assets	$ 658	$ 364
Lease liabilities, current	$ 363	$ 197
Lease liabilities, non-current	356	187
Total lease liabilities	$ 719	$ 384
Other information		
Weighted average remaining lease term	1.85 years	1.88 years
Weighted average discount rate	9.74%	8.25%
Supplemental cash flow information		
Operating cash outflows from operating leases	$ 244	$ 478

Maturities of lease liabilities as of December 31, 2025, were as follows (in thousands):

Year ending December 31,	
2026	$ 421
2027	370
2028	5
Total undiscounted lease payments	796
Less: imputed interest	(77)
Total lease liabilities	$ 719

As of December 31, 2025, the Company did not have any leases that have not yet commenced that create significant rights and obligations.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued payroll and other employee benefits	$ 1,464	$ 437
Other accruals	213	303
Nonclinical research	98	150
Clinical development	41	1,962
Income tax accruals	-	365
Biocon clinical development related to ulcerative colitis study - related party	-	223
Biocon and its subsidiaries chemistry, manufacturing and controls services - related party	-	43
Total accrued expenses	$ 1,816	$ 3,483

8. Partnerships

Asset Purchase Agreement with Ono Pharmaceutical Co., Ltd.

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

The Company was responsible for conducting all research and development of itolizumab, which had been funded by Ono from July 1, 2022 through October 30, 2024, the end of the option period. On October 30, 2024, the option period expired and the Asset Purchase Agreement automatically terminated pursuant to its terms.

During the year ended December 31, 2025, there was no revenue recognized under the Asset Purchase Agreement. During the year ended December 31, 2024, the Company recognized revenue of $41.1 million under the Asset Purchase Agreement. Such revenue was comprised of $28.3 million associated with development funding and $12.8 million associated with the amortization of the upfront payment during the year ended December 31, 2024.

Termination of Biocon Collaboration and License Agreement

On September 30, 2025 (the Termination Date), the Company entered into a termination agreement with Biocon Limited (Biocon and the agreement, the Termination Agreement) pursuant to which the Company and Biocon terminated the License Agreement, the Memorandum of Understanding dated April 7, 2022 and certain other corresponding agreements (collectively Biocon Agreements), with all licenses granted by Biocon to the Company under the Biocon Agreements, including with respect to itolizumab, terminating and reverting to Biocon. See Note 13 for additional details regarding the Biocon Agreements. As consideration for certain technical services the Company was obligated to provide to Biocon following the Termination Date, Biocon agreed to pay the Company a technical service fee of $0.4 million. In lieu of Biocon paying the technical service fee to the Company, Biocon set off amounts owed by the Company to Biocon under or in connection with the Biocon Agreements through the Termination Date, with the amount of such set-off to equal such technical service fee, plus any other amount that has been or may be invoiced by the Company to Biocon for work performed by the Company with respect to itolizumab through the Termination Date, and to be limited to the aggregate amounts that have been or may be invoiced by Biocon to the Company, or are or may be otherwise owed by the Company to Biocon, under or in connection with the Biocon Agreements through the Termination Date. The Company completed its performance obligations under the Termination Agreement in the fourth quarter of 2025, resulting in the set off of amounts owed by the Company to Biocon totaling $0.4 million which was recorded as a reduction of research and development expense in its consolidated statement of operations and comprehensive loss in the year ended December 31, 2025.

9. Stockholders' Equity

As of December 31, 2025, the Company's authorized capital stock consisted of 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

The Company had 61,464,368 and 35,557,563 shares of common stock outstanding as of December 31, 2025 and 2024, respectively.

Securities Purchase Agreement

On August 10, 2025, the Company entered into a Securities Purchase Agreement (the Purchase Agreement) with certain institutional and accredited investors (the Investors), pursuant to which the Company agreed to sell and issue shares (Shares) of the Company's common stock and pre-funded warrants to purchase shares of common stock (Warrant Shares), in up to two closings in a private placement transaction (the Private Placement).

The initial closing of the Private Placement occurred on August 12, 2025, (the Initial Closing). At the Initial Closing, the Company issued and sold 21,814,874 Shares at a purchase price of $0.57 per share (the Share Price) and pre-funded warrants to purchase up to 30,816,705 Warrant Shares at a purchase price of $0.5699 per Warrant Share (the Warrant Price) to the Investors for gross proceeds to the Company of approximately $30.0 million. Net proceeds from the Private Placement were $27.9 million, after deducting placement agent fees and offering expenses totaling $2.1 million.

Pursuant to the Purchase Agreement, subject to the occurrence of the Milestone Closing Trigger (defined below), the Investors have agreed to purchase at a closing (the Milestone Closing) up to 35,087,717 Shares or pre-funded warrants in lieu thereof at a purchase price per Share and pre-funded warrant equal to the Share Price and the Warrant Price, respectively, for gross proceeds to the Company of up to approximately $20.0 million. The Milestone Closing trigger means: (A) the achievement of either of the following prior to the five-year anniversary of the date of the Purchase Agreement (i) the clearance of an investigational new drug application for EQ504 or (ii) the dosing of the first patient in a single ascending dose or a multiple ascending dose trial of EQ504 in Australia or New Zealand (the first such event to occur, the Milestone Event), and (B) (x) the achievement of a volume weighted average price per share of $2.50 (subject to appropriate, proportional adjustment for any stock splits or combinations of the common stock occurring after the date of the Purchase Agreement) measured during any 10 consecutive trading days during the 30 trading days following the date the Company first announces via a press release or Current Report on Form 8-K the occurrence of the Milestone Event (such period the Measurement Period and such price threshold requirement, the Price Threshold), or (y) the Company's receipt of a waiver of

the Price Threshold signed by the Investors who hold a majority of the securities issued in the Private Placement (determined as if all of the Warrant Shares underlying pre-funded warrants then outstanding have been issued without regard to any limitations on the exercise of such pre-funded warrants) and delivered to the Company during the Measurement Period (the achievement or occurrence of (A) and (B) are collectively, the Milestone Closing Trigger). In the event the Milestone Closing Trigger occurs as a result of a Price Threshold Waiver, only the waiving Investors will be obligated to purchase Shares or pre-funded warrants at the Milestone Closing.

The pre-funded warrants have an exercise price of $0.0001 per Warrant Share, subject to customary adjustments, and are exercisable at any time and will not expire until exercised in full. The pre-funded warrants will also be exercisable on a net exercise "cashless" basis. The pre-funded warrants may not be exercised if the aggregate number of shares of common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation, not to exceed 19.99%.

The Company assessed the 30,816,705 pre-funded warrants issued at the Initial Closing and the 35,087,717 Shares or pre-funded warrants in lieu thereof to be issued at the Milestone Closing subject to the occurrence of the Milestone Closing Trigger and determined that they do not require liability classification pursuant to ASC 480. The pre-funded warrants at the Initial Closing and the Shares or pre-funded warrants contingent to be issued at the Milestone Closing do not have any net cash settlement provisions that would preclude equity classification under ASC 815-40. Accordingly, the pre-funded warrants were recorded to additional paid-in capital in the consolidated balance sheet. As of December 31, 2025 and through the date of the filing of this Annual Report on Form 10-K, the pre-funded warrants issued at the Initial Closing have not been exercised.

Registration Rights Agreement

In connection with the Private Placement, the Company entered into a Registration Rights Agreement (the Registration Rights Agreement) with the Investors at the Initial Closing, pursuant to which the Company agreed to prepare and file, within 30 days of the Initial Closing and, if applicable, the Milestone Closing, subject to certain allowable delays, one or more registration statements with the SEC to register for resale the Shares and, as applicable, the Warrant Shares, in each case that were issued under the Purchase Agreement, and generally to cause the applicable registration statements to promptly become effective. Certain cash penalties will apply to the Company in the event of registration failures.

On September 9, 2025, the Company filed a registration statement on Form S-3 (File No. 333-290138) for the resale of the Shares as well as the shares of common stock issuable upon the exercise of the pre-funded warrants that were issued at the Initial Closing, and it was declared effective on September 18, 2025.

2023 ATM Facility

In October 2023, the Company entered into an at-the-market facility 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 $21.95 million from time to time through Jefferies acting as the Company's sales agent (the 2023 ATM Facility). There were no shares sold under the 2023 ATM Facility from October 2023 through December 31, 2024. On August 3, 2025, the Company entered into Amendment No. 1 to the 2023 ATM Facility pursuant to which Jefferies was replaced by LifeSci Capital LLC as the sales agent under the 2023 ATM Facility. During the year ended December 31, 2025, there were 1,719,485 shares of common stock sold under the 2023 ATM Facility for gross proceeds of $1.0 million and net proceeds totaling $0.3 million, after deducting for issuance costs incurred inception-to-date of $0.7 million.

On September 19, 2025, the Company filed a prospectus supplement with the SEC under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $75.0 million, pursuant to the 2023 ATM Facility, as amended.

As of December 31, 2025 and through the date of the filing of this Annual Report on Form 10-K, there were no additional shares sold under the 2023 ATM Facility, as amended.

2018 Equity Incentive Plan

In October 2018, the Company adopted the 2018 Plan which replaced the Company's legacy 2017 Plan. The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other forms of stock awards. As of December 31, 2025, the 2018 Plan had a maximum of 292,972 total shares available for issuance. The number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each calendar year through January 1, 2028, in an amount equal to 5.0% of the total number of shares of the Company's capital stock outstanding, including, for purposes of this calculation, shares issuable upon exercise of outstanding pre-funded warrants, on

the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board.

Options granted under the 2018 Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option shall be determined by the Board based on the estimated fair value of the Company's stock on the date of the option grant. The exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. Most option grants generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years.

2024 Inducement Plan

On March 6, 2024, upon the recommendation of the Compensation Committee of the Company's board of directors, the Company's board of directors adopted and approved the Company's 2024 Inducement Plan (the Inducement Plan) to reserve 1,500,000 shares of the Company's common stock to be used exclusively for grants of equity awards to individuals that were not previously employees or directors of the Company (or who are returning to employment following a bona fide period of non-employment), as an inducement material to the individual's entry into employment with the Company, pursuant to Nasdaq Listing Rule 5635(c)(4). The Inducement Plan was adopted and approved without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). In addition, the Company's board of directors adopted and approved forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise for use with the Inducement Plan. The terms and conditions of the Inducement Plan are substantially similar to the Company's stockholder-approved 2018 Equity Incentive Plan (the 2018 Plan). As of December 31, 2025, there are 157,200 options outstanding under the 2024 Inducement Plan.

Stock Options

The following summarizes stock option activity for the year ended December 31, 2025:

	Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands) (a)
Balances as of December 31, 2024	9,023,792	$ 0.87		
Granted	6,430,200	$ 1.44		
Exercised	(2,372,446)	$ 0.78		
Forfeitures and cancellations	(2,666,985)	$ 0.89		
Balances as of December 31, 2025	10,414,561	$ 1.24	7.88	$ 4,502
Options exercisable as of December 31, 2025	4,046,879	$ 0.91	5.66	$ 2,990

(a) Aggregate intrinsic value in this table was calculated as the positive difference, if any, between the closing price per share of the Company's common stock on December 31, 2025 of $1.55 and the price of the underlying options.

For the years ended December 31, 2025 and 2024, the weighted-average grant date fair value of stock options granted per share was equal to $1.33 and $0.56, respectively.

As of December 31, 2025, unrecognized compensation expense related to unvested stock options was $7.7 million and is expected to be recognized over a weighted-average period of 3.5 years.

The total intrinsic value, which is the amount by which the exercise price was exceeded by the price of the Company's common stock on the date of exercise, of stock options exercised during the years ended December 31, 2025 and 2024 was $1.5 million and $2,000, respectively. Cash received from stock option exercises for the years ended December 31, 2025 and 2024 was $1.8 million and $4,000, respectively.

The fair value of stock options that vested in the years ended December 31, 2025 and 2024 was $1.7 million and $2.4 million, respectively.

2018 Employee Stock Purchase Plan

In October 2018, the Company adopted the 2018 Equity Stock Purchase Plan (ESPP) whereby eligible employees may elect to withhold up to 15% of their earnings to purchase shares of the Company's common stock at a price per share equal to the lower of (i) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (ii) 85% of the fair market value of a share of the Company's common stock on the date of the purchase right (purchase right). Initially, 343,275 shares of the Company's common stock were approved for issuance under the ESPP pursuant to purchase rights granted to the Company's employees or to employees of any of the Company's designated affiliates. The number of shares of the Company's common stock reserved for issuance will automatically increase on January 1 of each calendar year through January 1, 2028, by the lesser of (1) 1.0% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (2) 343,275 shares; provided that before the date of any such increase, the Board may determine that such increase will be less than the amount set forth in clauses (1) and (2).

As of December 31, 2025, the Company had issued 893,708 shares of common stock under the ESPP, none of which were issued during the year ended December 31, 2025. The Company had 1,369,497 shares available for future issuance under the ESPP as of December 31, 2025.

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 and comprehensive loss is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 716	$ 1,413
General and administrative	1,606	2,337
Total	$ 2,322	$ 3,750

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and non-employee stock option grants were as follows:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	3.99%	3.98%
Expected volatility	139.43%	79.10%
Expected term (in years)	6.06	6.03
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. For the year ended December 31, 2025, the expected volatility is based on the historical volatility of the Company's common stock over a period commensurate with the expected term of the Company's stock options. The Company determined that it had sufficient trading data and, therefore, concluded that its own historical volatility provides a more appropriate estimate of expected future volatility. For prior periods, due to the Company's limited operating history and lack of company-specific historical volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

Expected term. The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Expected dividend yield. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

Forfeitures. The Company reduces stock-based compensation expense for actual forfeitures during the period.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following as of December 31, 2025 and 2024:

	December 31,	
	2025	2024
Stock options issued and outstanding	10,414,561	9,023,792
Warrants for common stock	32,182,846	1,366,141
Common stock or pre-funded warrants subject to milestone closing	35,087,717	-
Awards available under the 2018 Equity Incentive Plan	292,972	340,109
Awards available under the 2024 Inducement Plan	1,342,800	1,500,000
2018 Employee Stock Purchase Plan	1,369,497	1,026,222
Total	80,690,393	13,256,264

10. Commitments and Contingencies

Leases and Other Commitments

As of December 31, 2025, the Company leased office space in La Jolla, California that expires in February 2027. The Company also leases laboratory space in San Diego that expires in January 2028. All of the Company's leased space is under non-cancelable operating leases.

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, 2025, there was no litigation against the Company.

11. Income Taxes

The components of loss before income tax provision for the years ended December 31, 2025 and 2024 consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
U.S.	$ (21,571)	$ (6,008)
Foreign	(827)	(1,698)
	$ (22,398)	$ (7,706)

During the year ended December 31, 2025, the Company did not record any federal or state tax expense. During the year ended December 31, 2024, the Company recorded a current federal and state tax expense of $340,000 and $21,000, respectively. During the years ended December 31, 2025 and 2024, the Company did not record a deferred federal or state income tax expense.

During the year ended December 31, 2025, federal and state income taxes paid, net of refunds, totaled $342,000 and $10,000, respectively.

The Company adopted ASU 2023-09 on a prospective basis beginning with the year ended December 31, 2025. The following is required disclosure pursuant to ASU 2023-09 and reconciles the U.S. federal statutory tax amount and rate to our effective amount and rate for the year ended December 31, 2025 (in thousands, except for percentages):

	Year ended December 31, 2025		
	Tax Effect	Effective Tax Rate	
Income taxes at statutory rates	$ (4,704)	21.0	%
State income tax, net of federal benefit [(a)]	(20)	0.1	%
Foreign tax effects:			
Australia:			
Valuation allowance	262	-1.2	%
Other	(87)	0.4	%
Tax credits:			
Research tax credits	(1,225)	5.5	%
Change in valuation allowance	4,000	-17.9	%
Nontaxable or nondeductible items:			
Permanent items	41	-0.2	%
Stock-based compensation	1,467	-6.6	%
Changes in unrecognized tax benefits	266	-1.1	%
Total	$ -	-	%

(a) State income taxes in California comprise the majority of the tax effect in this category.

The following is a reconciliation of the expected statutory federal income tax provision to our actual income tax provision prior to the adoption of ASU 2023-09 for the year ended December 31, 2024 (in thousands):

	Year Ended December 31, 2024
Income taxes at statutory rates	$ (1,618)
State income tax, net of federal benefit	(1,364)
Stock-based compensation	87
Officers compensation	122
Permanent items	101
Uncertain tax positions	564
Research and orphan drug credits	(1,146)
Foreign rate differential	488
Change in valuation allowance	3,127
Total	$ 361

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, 2025 and 2024 are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforward	$ 33,982	$ 27,546
Credits	10,953	10,009
Capitalized research expenditures	8,365	10,364
Other	1,559	3,136
Total deferred tax assets	54,859	51,055
Valuation allowance	(54,696)	(50,931)
Total deferred tax assets, net of allowance	$ 163	$ 124
Deferred tax liabilities:		
Operating lease right-of-use asset	(138)	(77)
Other	(25)	(47)
Total deferred tax liabilities	$ (163)	$ (124)

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 $54.7 million as of December 31, 2025, 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 $3.8 million during the year ended December 31, 2025.

At December 31, 2025, the Company had federal and state tax loss carryforwards of approximately $139.8 million and $92.1 million, respectively. The federal net operating loss carryover includes $139.8 million of net operating losses generated subsequent to 2017. Federal net operating losses, generated after December 31, 2017, carryover indefinitely but the deductibility of such federal net operating losses is limited to 80% of taxable income. The state net operating loss carryforwards, begin to expire in 2038 unless previously utilized. The Company has $5.0 million of Australian net operating loss carryforwards as of December 31, 2025, that are carried forward indefinitely.

At December 31, 2025, the Company had federal and state tax credit carryforwards of approximately $10.6 million and $3.3 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 2035, if unused, and the state credits carryforward indefinitely.

Pursuant to the Internal Revenue Code of 1986, as amended (IRC), specifically Sections 382 and 383, the Company’s ability to use tax attribute carryforwards to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company completed an ownership change analysis through December 31, 2024, pursuant to IRC Section 382 and determined that the Company’s ability to offset taxable income in 2024 is not expected to be impacted by ownership changes occurring prior to that date. Due to our estimated U.S. tax loss for the year ended December 31, 2025, we do not expect to utilize tax attribute carryforwards in 2025. If ownership changes within the meaning of IRC Section 382 occur in the future, the amount of remaining tax attribute carryforwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, the Company's deferred tax assets associated with such tax attributes could be significantly reduced or eliminated upon realization of an ownership change within the meaning of IRC Section 382. If eliminated, the related asset would be removed from the deferred tax asset schedule, with a corresponding reduction in the valuation allowance. Additionally, limitations on the utilization of the Company's tax attribute carryforwards can increase the amount of taxable income and current income tax expense recognized. Due to the existence of the valuation allowance, ownership change limitations that are not significant may not impact the Company's effective tax rate.

The following table summarizes the reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Unrecognized tax benefits – beginning	$ 6,920	$ 6,075
Gross increases – tax positions in prior period	-	580
Gross increase – current-period tax positions	271	265
Unrecognized tax benefits – ending	$ 7,191	$ 6,920

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets and tax payables. As of December 31, 2025 and 2024, the Company had unrecognized tax benefits totaling $0.6 million, which, if recognized, would affect the Company's effective tax rate.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's consolidated balance sheet as of December 31, 2025, and has not recognized interest and/or penalties in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

All tax years for both federal and state purposes remain open and subject to examination by tax jurisdictions. The Company is subject to taxation in the United States, various U.S. state jurisdictions and Australia.

During the year ended December 31, 2025, the Company had no income tax expense. During the year ended December 31, 2024, the Company's income tax expense was $0.4 million. The Company's 2024 income tax expense was primarily attributable to domestic cash tax expense resulting from differences between book and tax treatment of certain items. The Company does not record a deferred tax provision as there is a full valuation allowance offsetting the Company's net deferred tax assets.

The One Big Beautiful Bill Act (OBBBA) enacted on July 4, 2025, introduced notable changes to the U.S. Internal Revenue Code, including immediate expensing of domestic Section 174 costs while foreign costs will continue to be capitalized and amortized over 15 years. Section 174 costs are expenditures which represent research and development costs that are incident to the development or improvement of a product, process, formula, invention, computer software, or technique. With the enactment of OBBBA, the Company began deducting domestic Section 174 costs in 2025.

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 did not make any contributions for the years ended December 31, 2025 or 2024.

13. Related Party Transactions

On September 30, 2025, the Company entered into a Termination Agreement with Biocon with all licenses granted by Biocon to the Company under the Biocon Agreements, including with respect to itolizumab, terminating and reverting to Biocon. Refer to Note 8 for additional details. As of December 31, 2025, Biocon no longer holds more than 5% of the Company's common stock and is no longer considered a related party. Biocon was a holder of more than 5% of the Company's common stock in prior periods.

In April 2022, the Company entered into an agreement with Biocon to collaborate on and co-fund a Phase 2 clinical study of itolizumab in subjects with ulcerative colitis that was being conducted by Biocon in India. The Company's share of the total clinical study costs was approximately $1.4 million. During the years ended December 31, 2025 and 2024, the Company recorded a net reduction of research and development expenses of $0.2 million and recognized $0.4 million of research and development expenses, respectively, related to its portion of the total clinical study costs. The reduction in 2025 resulted from the reversal of amounts owed to Biocon pursuant to the Termination Agreement. As of December 31, 2025, no amounts were accrued or invoiced by and payable to Biocon related to this clinical study, compared to accrued expenses of $0.2 million and no amounts invoiced by and payable to Biocon as of December 31, 2024.

In February 2020, the Company entered into a master services agreement with Syngene International Limited (Syngene), a wholly-owned subsidiary of Biocon, for chemistry, manufacturing and controls (CMC) services associated with itolizumab development (the Syngene MSA). In July 2023, the Company issued a work order under the Syngene MSA totaling $5.4 million for CMC activities, substantially all of which was paused in the third quarter of 2024. In 2024, the Company also entered into a work order for stability studies with Syngene totaling $0.1 million as well as purchase orders for CMC projects and purchases of drug product with Biocon totaling approximately $6.5 million, the majority of which was paused as of October 30, 2024. During the years ended December 31, 2025 and 2024, the Company recognized a net reduction of research and development expenses of $29,000 and recognized $3.7 million of research and development expenses, respectively, related to these CMC agreements. As of December 31, 2025, no amounts were accrued, invoiced by or payable to Biocon or Syngene, compared to accrued expenses of $43,000 and amounts invoiced by or payable to Biocon and Syngene of $0.6 million as of December 31, 2024.

The majority of the aforementioned expenses incurred in the prior year associated with work performed by Biocon or its affiliates related to itolizumab development were reimbursed by Ono pursuant to the terms of the Asset Purchase Agreement during the Ono option period which expired on October 30, 2024.

The Company classifies its accruals related to these activities as accrued expenses on the accompanying consolidated balance sheets. The Company classifies amounts invoiced by and payable to Biocon and Syngene as accounts payable on the accompanying consolidated balance sheets.

14. Segment Reporting

The Company operates through a single operating and reportable segment focused on the business of developing novel therapies to treat severe autoimmune and inflammatory disorders with the mission to develop life-changing therapeutics for patients. The Company manages all business activities on a consolidated basis. The Company's chief operating decision maker (CODM) is the Chief Executive Officer.

The accounting policies of the operating segment are the same as those described in Note 2, Summary of Significant Accounting Policies. The CODM evaluates the performance of the operating segment and allocates resources based on net loss that also is reported on the consolidated statements of operations and comprehensive loss as net loss. The measure of the operating segment assets is reported on the consolidated balance sheets as total assets.

The CODM uses net loss to monitor budget versus actual results and to analyze cash flows in assessing performance of the segment and allocating resources. The significant expense categories regularly provided to the CODM include research and development and general and administrative expenses. These expense categories are reported as separate line items in our consolidated statements of operations and comprehensive loss. All our revenue is attributable to the United States and to our single operating segment.

15. Subsequent Events

On March 11, 2026, the Company entered into a Securities Purchase Agreement (the March Purchase Agreement) with an institutional and accredited investor (the March Investor). At the closing on March 13, 2026, the Company issued and sold 1,179,508 shares of the Company's common stock for a purchase price of $1.854 per share and a pre-funded warrant to purchase 17,698,593 shares of common stock at a purchase price of $1.8539 per share, with an exercise price of $0.0001 per share, in each case to the March Investor for gross proceeds of approximately $35.0 million. In connection with the issuance and sale of the shares and pre-funded warrant, the Company granted the March Investor customary registration rights pursuant to the Registration Rights Agreement dated March 13, 2026.

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EXECUTIVE TEAM

Bruce Steel, CFA
Chief Executive Officer and Director

Stephen Connelly, Ph.D.
President and Chief Scientific Officer

Christine Zedelmayer
Chief Operating Officer

Penny Tom, CPA
SVP Finance and Principal Accounting Officer

BOARD OF DIRECTORS

Daniel M. Bradbury
Chairman

Peter Colabuono
Director

Martha J. Demski
Director

Charles McDermott
Director

Mark Pruzanski, M.D.
Director

Bruce Steel, CFA
Chief Executive Officer and Director

Barbara Troupin, M.D.
Director

CORPORATE HEADQUARTERS

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ANNUAL MEETING OF STOCKHOLDERS

Wednesday, May 28, 2026
1:00 P.M. (Pacific Time) via live webcast
Go to www.proxydocs.com/EQ to register for the virtual meeting

COMMON STOCK LISTING

Nasdaq Capital Market
Ticker Symbol: EQ

INVESTOR RELATIONS

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NOTE ON FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of the United States securities laws. Such forward-looking statements are subject to risks and uncertainties that could cause Equillium's actual results to differ materially from those indicated by these forward-looking statements. Information on the risks and uncertainties that could affect Equillium's results is included in the Annual Report on Form 10-K included herewith. Equillium undertakes no obligation to update any forward-looking statements.

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